IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC., Plaintiff, v. RYMED TECHNOLOGIES, INC., Defendant.	)	Civil Action No. 07-468-JJF

DECLARATION OF KIMBERLY VAN VOORHIS IN SUPPORT OF ICU'S OPPOSITION TO RYMED'S MOTION FOR REARGUMENT

I, Kimberly Van Voorhis, declare and state as follows:

I am attorney in the law firm of Morrison & Foerster LLP, counsel of record for Plaintiff ICU Medical, Inc. ("ICU") in the above-referenced matter. I have personal knowledge of all the facts contained herein and, if called to testify, could and would competently testify thereto.

1. On November 30, 2007, ICU filed a motion to dismiss or in the alternative stay the California action pending this Court's decision on RyMed's motion to transfer venue. ICU's reply brief in support of its California motion was due on Monday, January 28, 2008.

2. On January 23, 2008, after this Court issued its Order denying transfer, I left a voice mail message with Scott Wales, RyMed's counsel, regarding the Order and ICU's motion to dismiss.

3. On January 24, 2008, I spoke with Mr. Wales regarding the California litigation and asked if RyMed would stipulate to a dismissal without prejudice of all claims pending in the California action. Mr. Wales stated that RyMed was not able to stipulate at that time. He did not ask for a meet and confer regarding RyMed's motion for reargument at this time.

4. On Monday, January 28th, ICU filed its reply in support of its motion to dismiss in the Central District of California.

5. After ICU filed its reply, Judge Pfaelzer's clerk contacted counsel for ICU to request a telephonic conference on ICU's motion. That hearing was held on January 30, 2008. A true and correct copy of the transcript of that hearing is attached hereto as Exhibit A. During that hearing, ICU learned for the first time that RyMed intended to file a motion for reargument. There was no mention of any allegedly "new" fact during the hearing.

6. On January 31st, Mr. Wales left me a voice mail in an effort "meet and confer" on the motion for reargument. He did not mention that RyMed had obtained a new fact.

7. I returned his call, leaving a voicemail indicating that ICU would oppose the motion for reargument based on the facts as it understood them. At this time, I was unaware that any allegedly "new fact" had been found.

8. On February 1st, Mr. Wales and I spoke regarding the schedule in this case. At the end of the call, I asked him when he intended to file the motion for reargument. He stated that they had gotten a bit delayed because of a "new fact." I asked him if he would tell me the allegedly "new" fact that RyMed had uncovered but he declined to share it with me.

9. I also spoke with Mr. Wales prior to RyMed's filing of its motion for reargument and again asked if he would share the new fact with ICU and Mr. Wales declined.

10. The *Alaris* litigation began in front of Chief Judge Alice Stotler in the Central District of California and the first 306 items on the docket were before that Court. Judge Pfaelzer heard the remaining motions.

11. Attached hereto as Exhibit B is a true and correct copy of United States Patent No. 6,994,315 assigned to RyMed Technologies.

12. Attached hereto as Exhibit C is a true and correct copy of a letter from the FDA to RyMed dated February 9, 2007.

13. Attached hereto as Exhibit D is a true and correct copy of Co-Medical, Inc.'s contact information as listed on the Goliath business information resource website at http://goliath.ecnext.com/coms2/product-compint-0000908004-page.html.

14. Attached hereto as Exhibit E is a true and correct copies of a pages from Fluidnet's website, www.fluidnet.net.

15. Attached hereto as Exhibit F is a true and correct copy of Fluidnet's registration with the Delaware Secretary of State.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed in Aspen, CO on February 24, 2008.

Kimberly Van Voorhis

pa-1229370

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on February 25, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on February 25, 2008, the attached document was Electronically Mailed to the following person(s):

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811768 / 32116

EXHIBIT A

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA - WESTERN DIVISION

HONORABLE MARIANA R. PFAELZER, U.S. DISTRICT JUDGE

- - -

COPY

RYMED TECHNOLOGIES, INC., PLAINTIFF, vs. ICU MEDICAL, INC., DEFENDANT.	No. SA CV07-1199-MRP(MLGx)

REPORTER'S TRANSCRIPT OF TELEPHONIC PROCEEDINGS

LOS ANGELES, CALIFORNIA

WEDNESDAY, JANUARY 30, 2008

CINDY L. NIRENBERG, CSR 5059
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LOS ANGELES, CALIFORNIA; WEDNESDAY, JANUARY 30, 2008

12:04 P.M.

- - - - -

THE CLERK: Good morning, Counsel. In the matter of case number SA CV07-1199-MRP, Rymed Technologies, Inc., versus ICU Medical.

Counsel, state your appearances for the record.

MR. BUNSOW: Good morning, Your Honor. This is Henry Bunsow for Rymed, and with me is -- or are Mr. K.T. Cherian and Mr. Scott Wales.

MS. VAN VOORHIS: Good morning, Your Honor. This is Kimberly Van Voorhis representing ICU Medical, and with me are Diana Luo and Dan Wan.

THE COURT: I called you to avoid having to get together with you on the date now set. I want to just say that I have read the decision of the judge in Delaware, and I am prepared to dismiss this case. I only have just a slight problem that I want to talk to you about and that is those claims that have to do with state law causes of action. They appear to be part of the patent case, and I want to talk about what would happen if I dismissed -- if I granted this motion to dismiss. So let's just start out and ask you, Ms. Van Voorhis, what then?

MS. VAN VOORHIS: What the effect of --

THE COURT: Well, no.

MS. VAN VOORHIS: ICU's position is that all of the claims should be dismissed, so --

THE COURT: Well, but these are without prejudice dismissals, aren't they?

MS. VAN VOORHIS: Yes.

THE COURT: Well, you would have no objection, would you, on behalf of ICU to their amending and adding whatever they want to from this complaint to the one in Delaware?

MS. VAN VOORHIS: That's certainly true, Your Honor, with the one caveat that ICU's position is that we don't believe regardless of where some of those claims are brought -- for example, the trademark claim, we don't believe that those claims are proper at the outset. But, certainly, we would not object to allowing Rymed to amend its answer and counterclaim in Delaware to add any claims that it wishes, provided, you know, we reserve our right to challenge those claims.

THE COURT: All right. What do you say, Mr. Bunsow?

MR. BUNSOW: Your Honor, out of the 21 claims in the complaint, 13 of them are not in the Delaware action.

They do include the state court-based claims that you've alluded to, but they also include non-infringement claims relating to our new product which is not and could not have been in the original Delaware action because it was not on the market when the Delaware action was filed, so it's really more than just the state court claims.

We feel that we've got a right to a determination, at least as to the new product before Your Honor, given Your Honor's long history with this case.

THE COURT: Well, that's not -- is that what you got sued for in Delaware?

MR. BUNSOW: No. We got sued in Delaware on the old product, but the case law is very clear that a new product does allow a declaratory judgment action in these circumstances where we've already been sued on a predecessor product.

So a declaratory judgment action -- I mean, jurisdiction is available. It is part of the California case before Your Honor. It is not part of the complaint that's in Delaware, and we think it could be disposed of very quickly and very efficiently given Your Honor's prior involvement and familiarity with this case.

As an example, they have sued us on 80, eight zero, individual claims in Delaware and Your Honor's Markman construction in the prior case would eliminate almost 60 of those from consideration of infringement.

So there is a huge difference between what -- if this case is -- if they are bound by what happened in the prior case, given Your Honor's familiarity. And as to our new product, we would certainly like to take advantage of those judicial efficiencies.

Now, I'll also mention that we plan to seek

reconsideration of Judge Farnan's denial of our motion to transfer; and if necessary, we are seriously considering taking a writ because we think it is a very strong motion to transfer. We think there are legions of reasons why this case should be before Your Honor instead of a new judge in a district forum where neither party is a resident and there is almost no activity whatsoever, so --

THE COURT: Well, what -- go on, Mr. Bunsow. Go on.

MR. BUNSOW: That chapter is not over yet, is what I am saying. We don't believe that it's a sure thing that this case is going to go forward in Delaware at all.

We believe that we have at least a fair chance of persuading Judge Farnan by way of a motion for reconsideration that might better state what we tried to say the first time around.

But more importantly, we think that the case law supports a transfer, and that, frankly, what he has done is an abuse of discretion, and we are strongly recommending to the client that they authorize us to take that by way of a writ to the CAFC if necessary.

THE COURT: What do you say, Ms. Van Voorhis?

MS. VAN VOORHIS: Several comments in response, Your Honor.

First, I believe the Court's question was what to do about the state law claims, and the patent infringement claims

are the federal claims, and as we've indicated in our opening brief, as well as I am looking at our reply brief here, at least on Page 3, the modified product is most certainly covered by the Delaware case, and we have cited a case to support this.

And also Judge Farnan, I don't believe his order references or makes any distinction at all between the modified product and the original product because they are, in fact, the same and all already covered under the Delaware action.

So that is my response there on the patent side of things. I think that's already very clearly covered by Judge Farnan.

And with respect to whether to seek a writ, you know, that's --

THE COURT: Oh, well, I'm not asking you to comment about that.

MS. VAN VOORHIS: Okay. Thank you. I didn't know.

THE COURT: Well, let's continue the motion, then, and let you do whatever you want to, Mr. Bunsow.

I don't think I want to take a position about this. I want you both to be able to enunciate your positions back there in Delaware. And so I suggest that you stipulate to a continuance of the motion, and we will get together after Delaware has said something definitive or denied that it will do so.

MR. BUNSOW: That's what we would definitely prefer,

Your Honor. That's fine with us.

THE COURT: Okay. Then why don't you do that. Why don't you stipulate and send it in to me.

MR. BUNSOW: All right. We'll write up a stipulation today and get it over to Ms. Van Voorhis for her approval.

THE COURT: Is that agreeable, with you, Ms. Van Voorhis?

MS. VAN VOORHIS: I think if that's the Court's preference, that's fine. However, I do think that ICU has a very serious patent infringement claim out here, and I want to express some serious concern about what appears to me to be just an effort to delay this, and so I do not want something -- some type of a stipulation that's open-ended. I don't think that's fair. I think we have a very serious infringement case, and I don't know -- I don't know what sort of timing Rymed is looking at in terms of bringing --

THE COURT: Well, let's --

MS. VAN VOORHIS: -- any type of motion for reconsideration. I don't know how serious that is. I know it's a very, very high standard, and I think it would be very unlikely that Judge Farnan would reconsider. But, nevertheless, my one concern is how long this is going to delay the ultimate resolution of ICU's case.

THE COURT: Well, I'm going to leave that to both of you, and I want that sent in to me right away so that I get it

no later than Monday morning. And if you can't continue it -- if you can't figure out a date between you, you call the clerk and tell her that, and then I will continue it.

MR. BUNSOW: Your Honor, this is Henry Bunsow. I think we could agree on an arbitrary date, say, 30 days, with the understanding that if either Judge Farnan hasn't acted or it's still in play, we could either jointly or unilaterally request a further continuance. I mean, that's the way I'd like to do it. That way it's not left up in the air.

THE COURT: That's fine with me. Is that all right with you, Ms. Van Voorhis?

MS. VAN VOORHIS: To be frank, Your Honor, it's something I'd like to discuss with my team. Mr. Pooley's not here, and that's something that I would prefer to discuss with ICU, but I will certainly do so promptly and will in good faith discuss it with Rymed's counsel.

THE COURT: And so we will hear from you right away?

MS. VAN VOORHIS: Yes.

THE COURT: Right?

MS. VAN VOORHIS: Yes. Yes. Oh, of course, yes.

THE COURT: All right. Then we are not -- don't come on the date now set, and I'll expect to hear from you. Yes?

MR. BUNSOW: Yes, Your Honor.

MS. VAN VOORHIS: Yes, Your Honor.

THE COURT: All right. Thank you.

MS. VAN VOORHIS: Thank you, Your Honor.

MR. BUNSOW: All right. Thank you.

(Proceedings concluded.)

--oOo--

CERTIFICATE

I hereby certify that pursuant to Section 753, Title 28, United States Code, the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Date: February 1, 2008

_____

Cindy L. Nirenberg, CSR No. 5059

EXHIBIT B

US006994315B2

(12) **United States Patent**
Ryan et al.

(10) **Patent No.: US 6,994,315 B2**
(45) **Date of Patent: Feb. 7, 2006**

(54) **SWABBABLE NEEDLE-FREE INJECTION PORT VALVE SYSTEM WITH NEUTRAL FLUID DISPLACEMENT**

(75) Inventors: **Dana Wm. Ryan**, Nolensville, TN (US); **David P. Gordon**, Stamford, CT (US); **James M. Kaiser**, Austin, TX (US); **Frank A. Scarfone**, Miramar, FL (US)

(73) Assignee: **Rymed Technologies, Inc.**, Nolensville, TN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 80 days.

(21) Appl. No.: **10/756,601**

(22) Filed: **Jan. 13, 2004**

(65) **Prior Publication Data**

US 2005/0151105 A1 Jul. 14, 2005

(51) **Int. Cl.**
F16K 59/00 (2006.01)
F16L 29/00 (2006.01)
F16L 37/28 (2006.01)

(52) **U.S. Cl.** **251/149.6**; 251/149.3; 251/149.8; 604/249; 604/256

(58) **Field of Classification Search** 251/149.1, 251/149.3, 149.4, 149.6, 149.8; 604/246, 604/249, 256, 95.04, 95.05, 523, 528, 533, 604/534, 535, 537, 538, 539, 905; 600/433, 600/434, 435, 585
See application file for complete search history.

(56) **References Cited**

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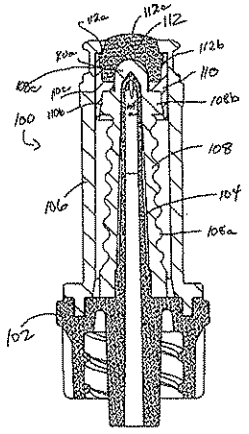
* cited by examiner

Primary Examiner—Edward K. Look
Assistant Examiner—John K. Fristoe, Jr.
(74) *Attorney, Agent, or Firm*—Gordon & Jacobson, PC

(57) **ABSTRACT**

An improved needle-free intravenous injection port assembly is disclosed. Embodiments include a boot valve with a helical surface, a boot valve and septum which mate with mechanical interference, a spike with a rough outer surface coated with a lubricant, a septum having a shoulder and a single continuous swabbable surface, a septum and a boot valve which are pre-punctured with a solid core steel needle, a septum with a frustroconical extension and a combination single piece septum and boot valve. The injection port assembly provides neutral fluid displacement during coupling and uncoupling.

30 Claims, 17 Drawing Sheets



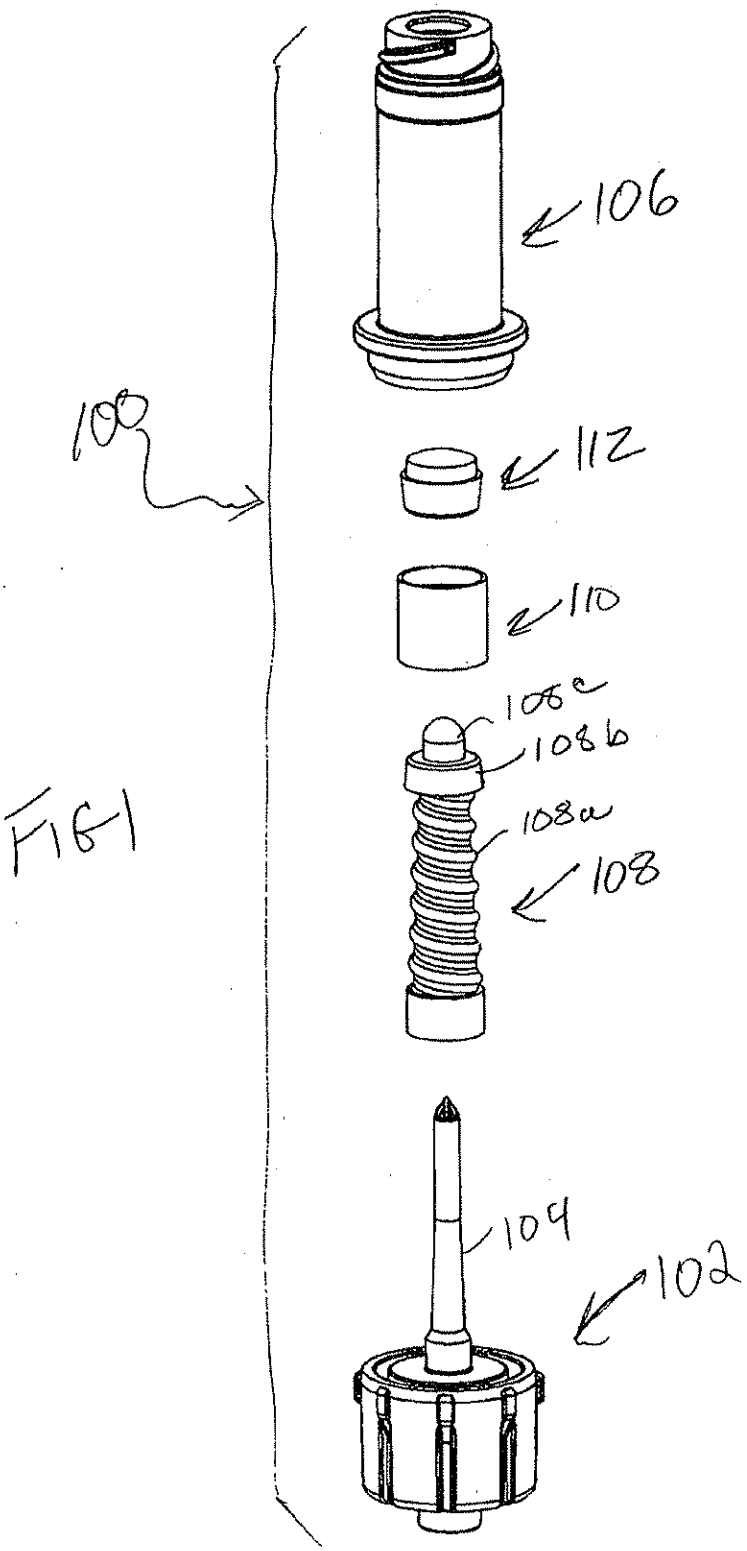


FIG 1

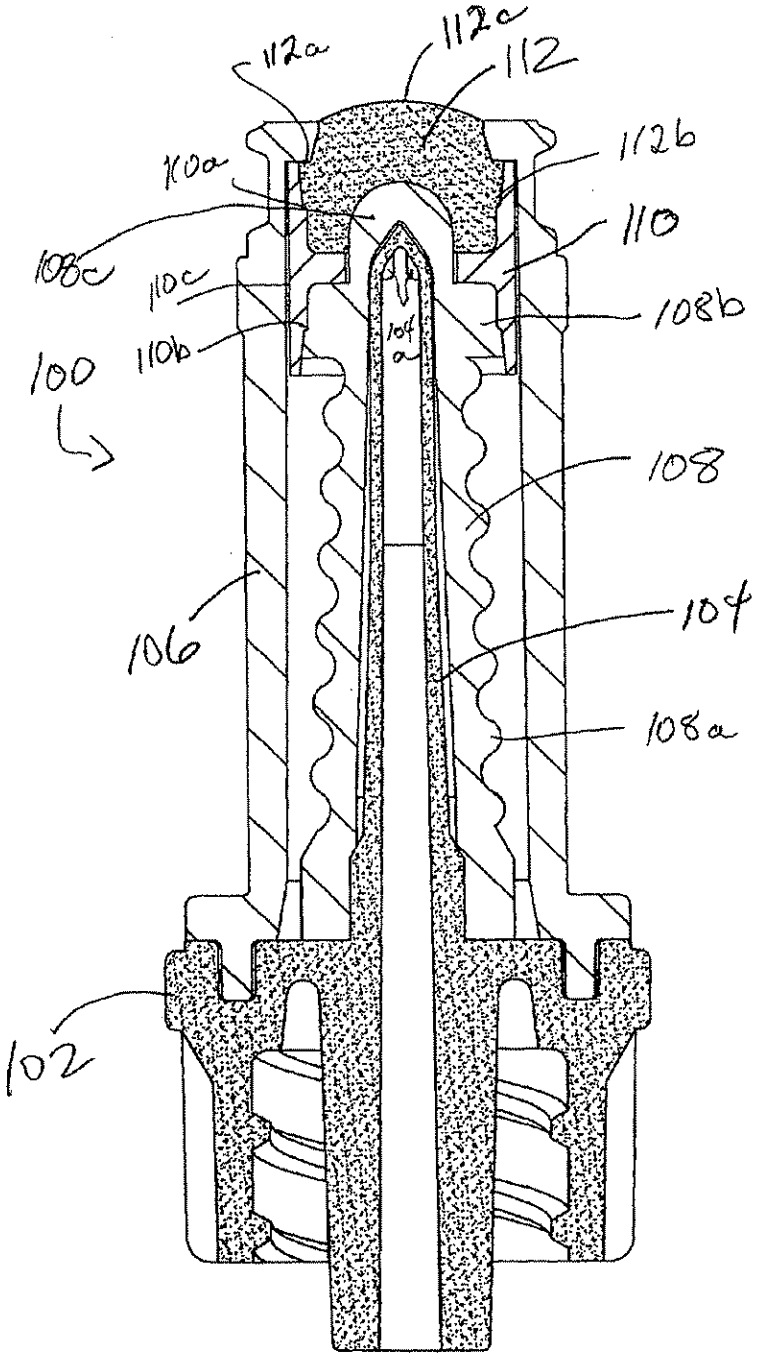

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FIG. 2

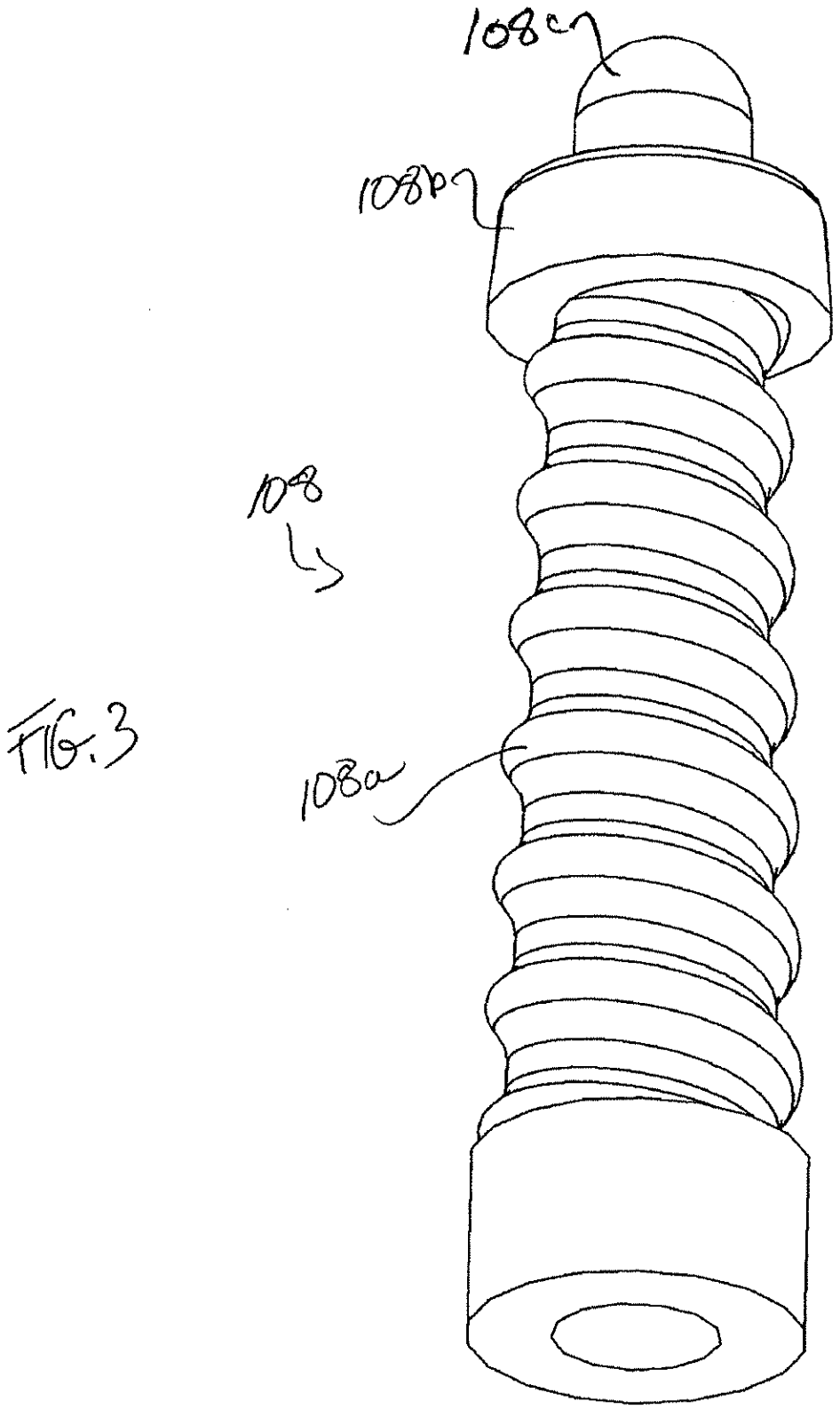


FIG. 3

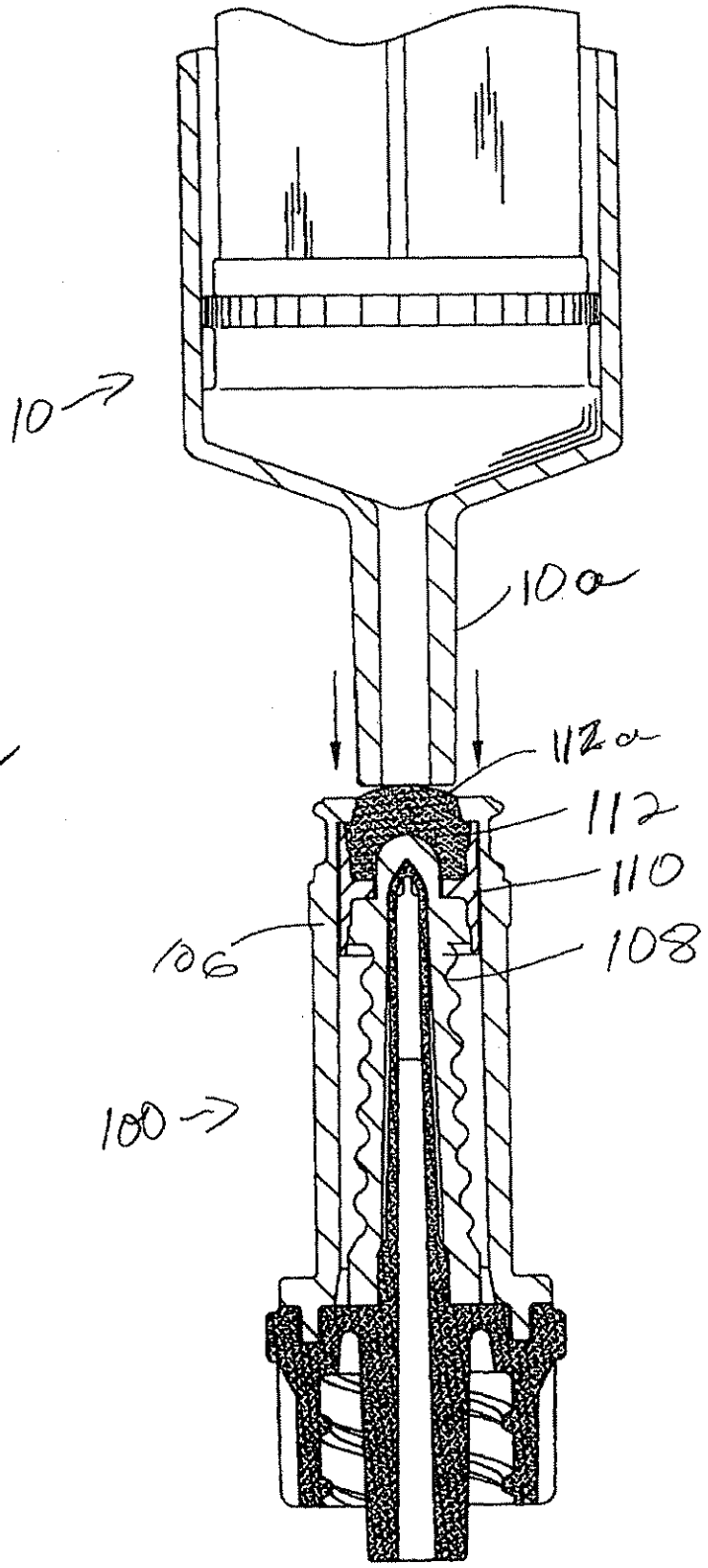
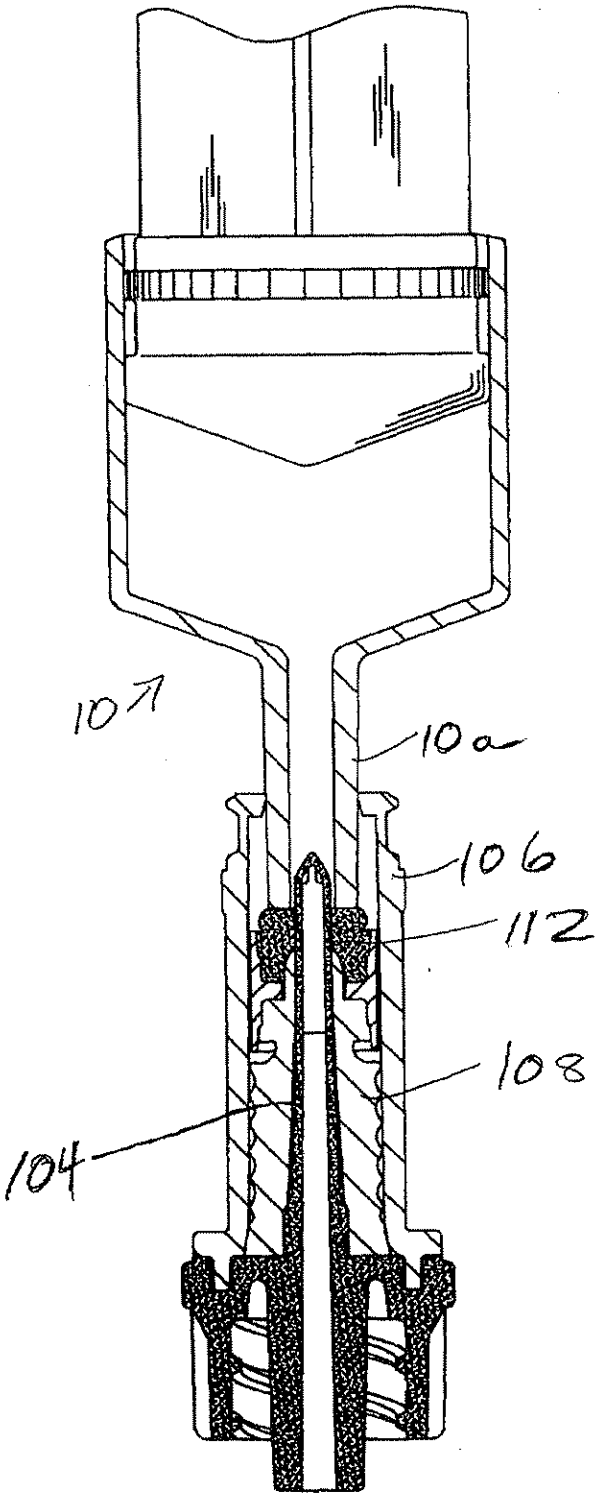


Figure 4

Figure 5



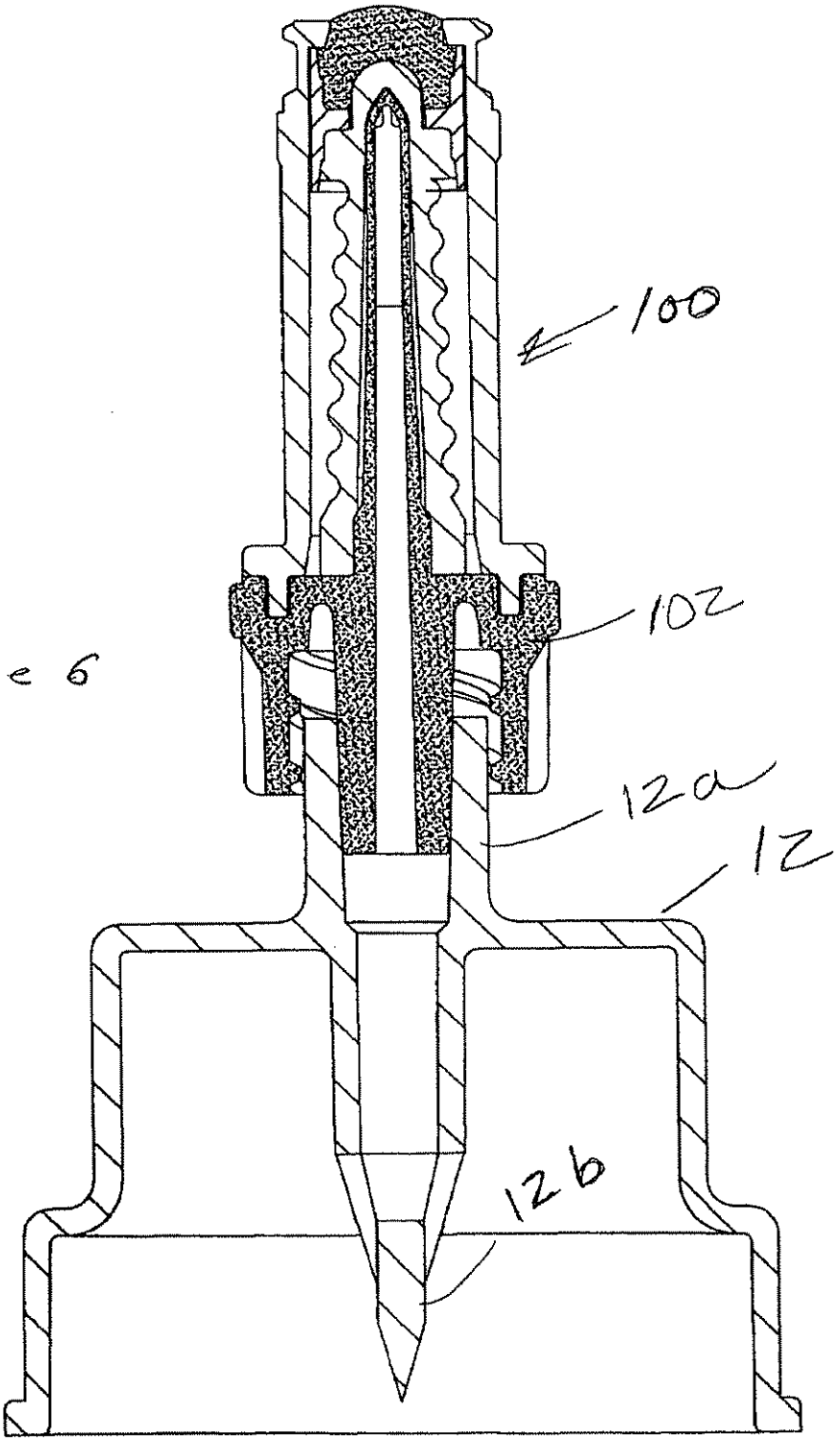


Figure 6

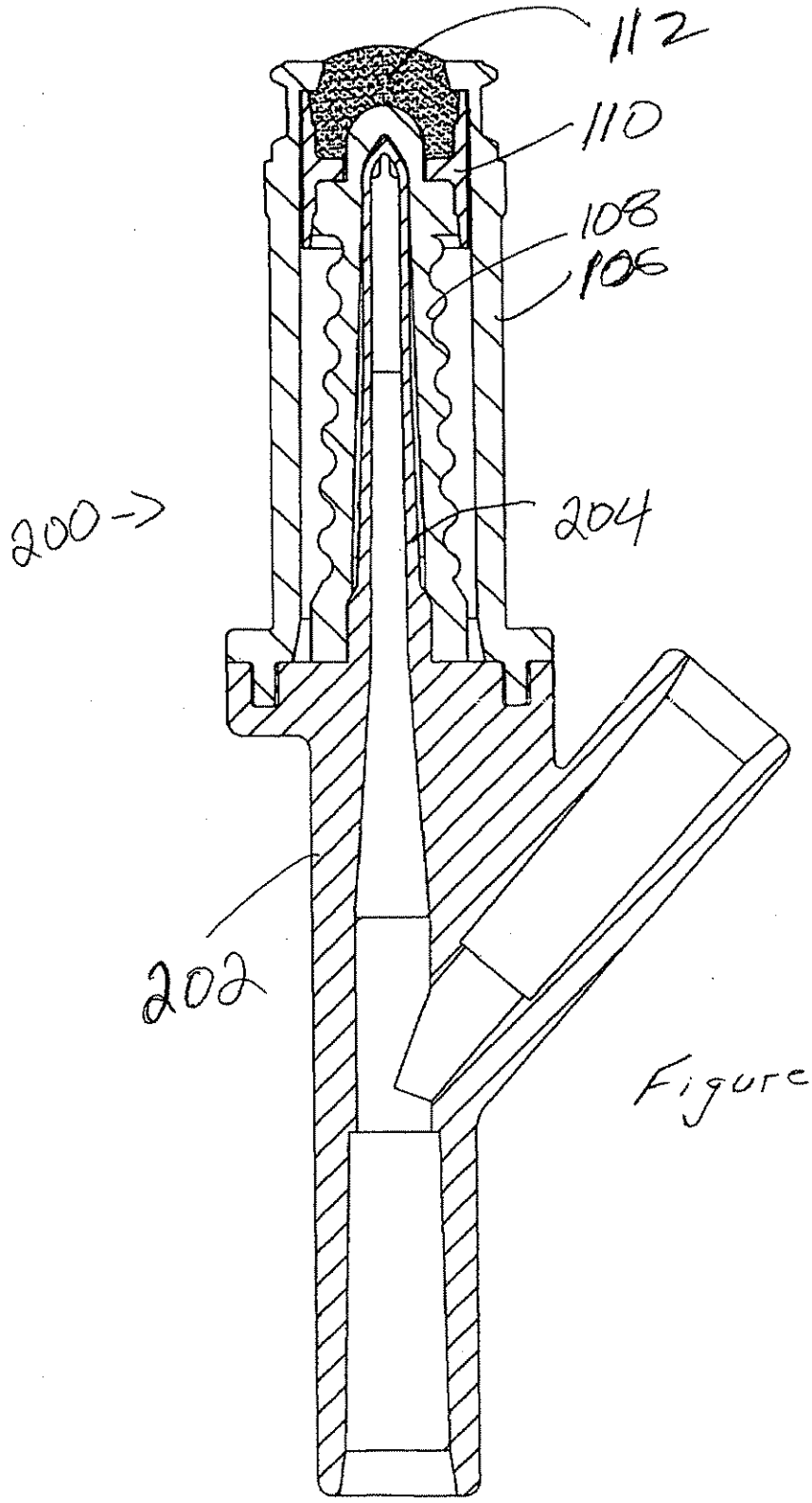


Figure 7

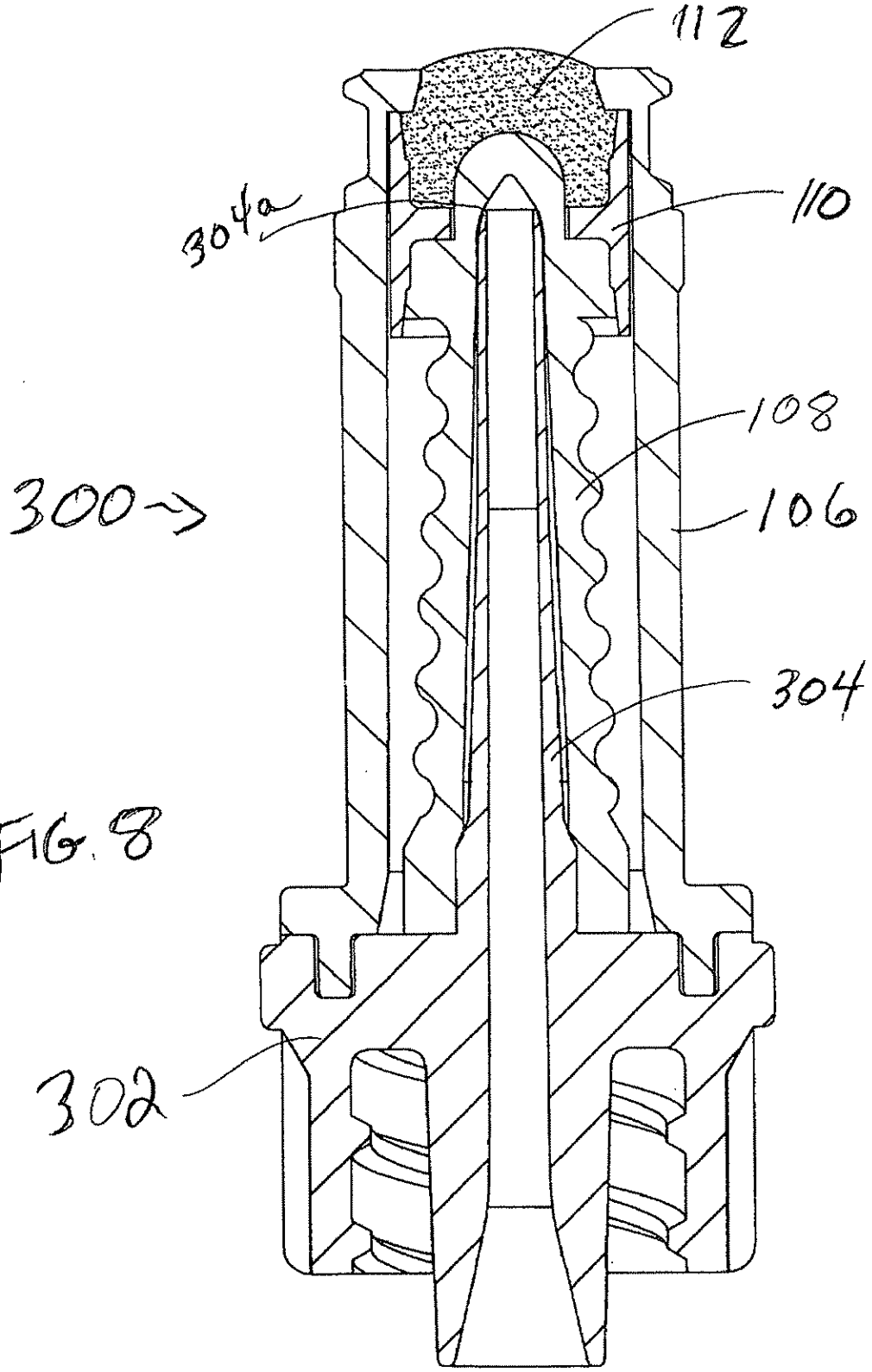


FIG. 8

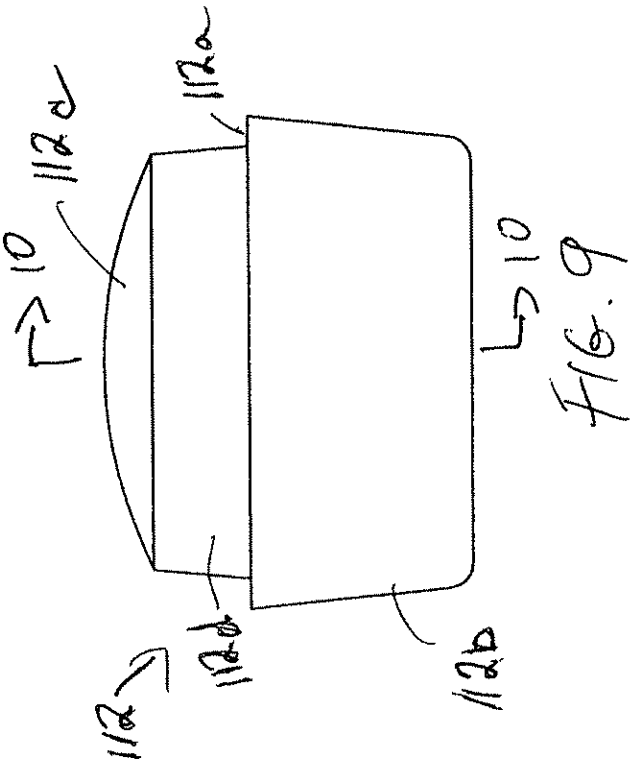


FIG. 9

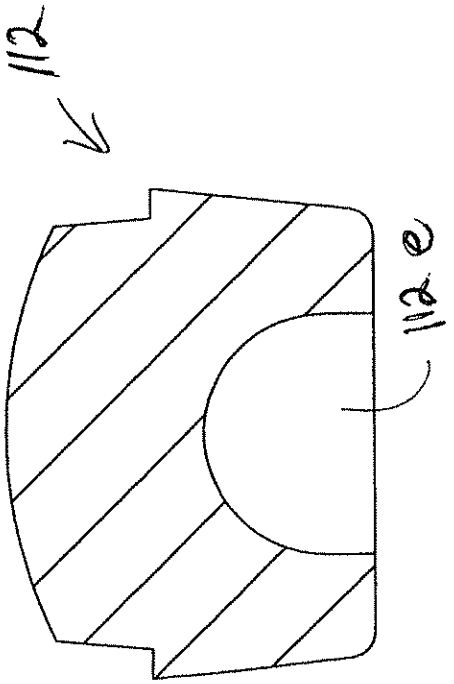


FIG. 10

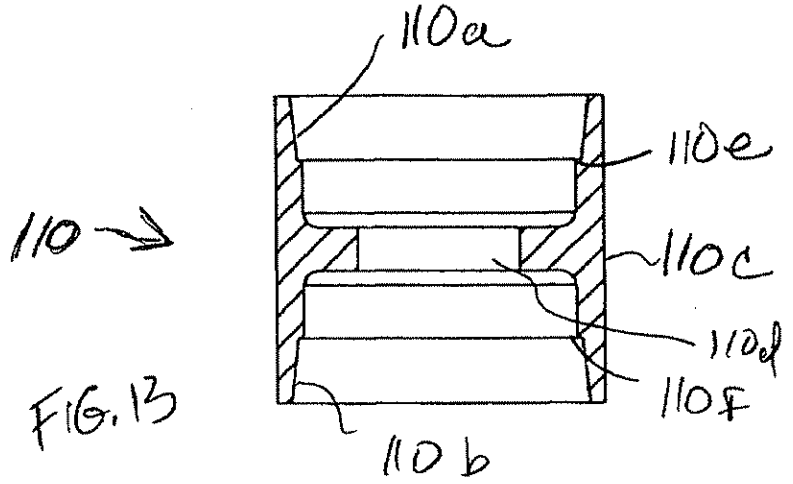


FIG. 13

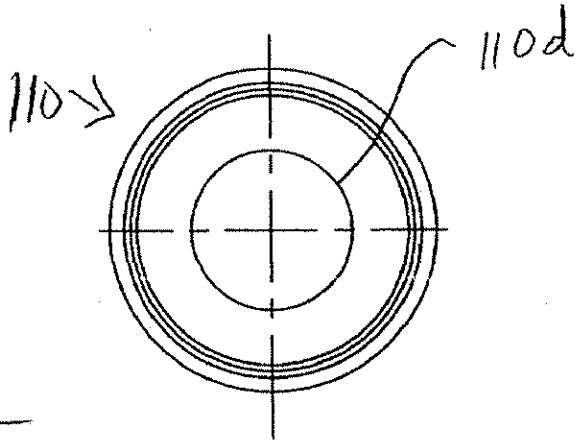


FIG. 12

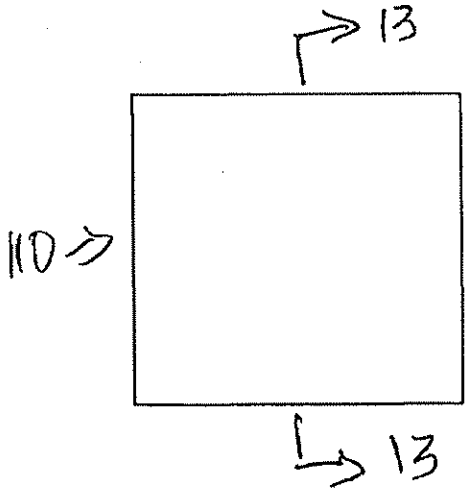


FIG. 11

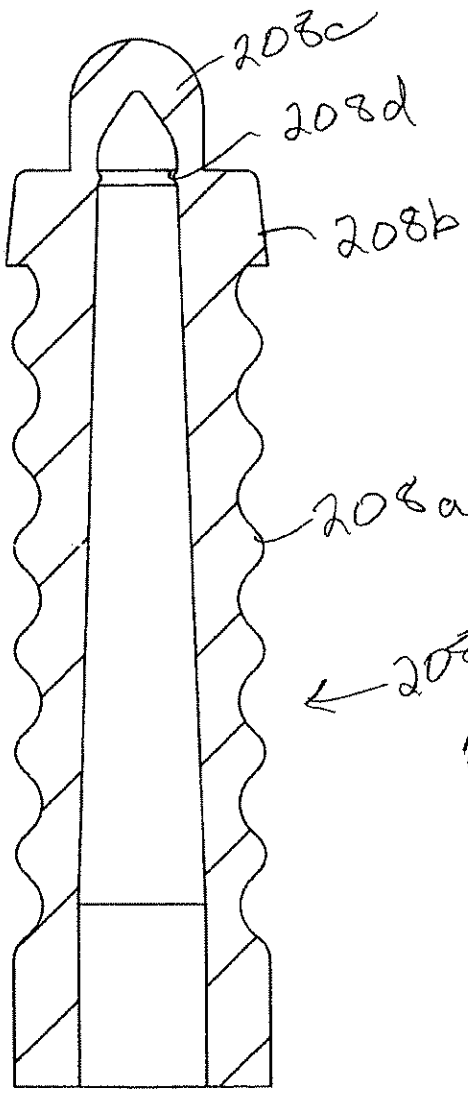


FIG. 15

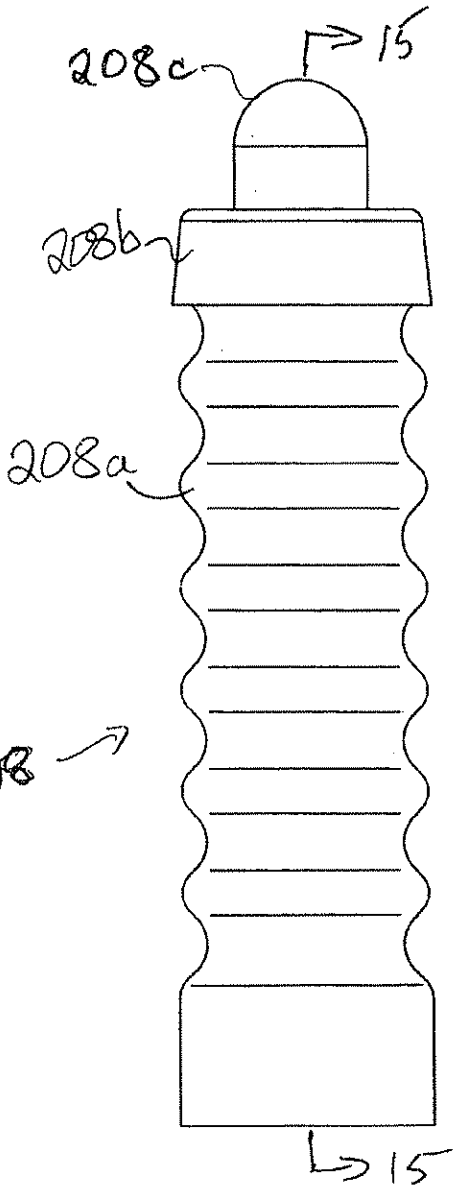


FIG. 14

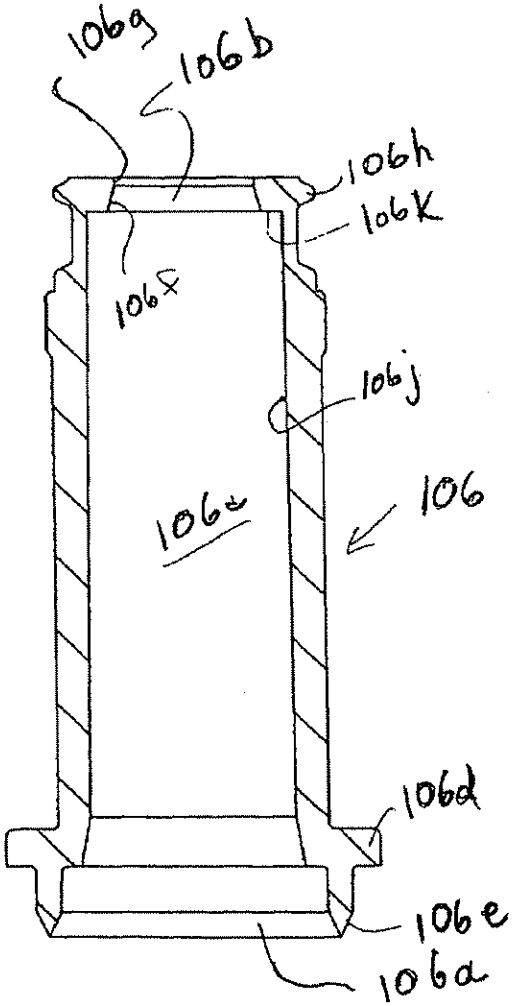

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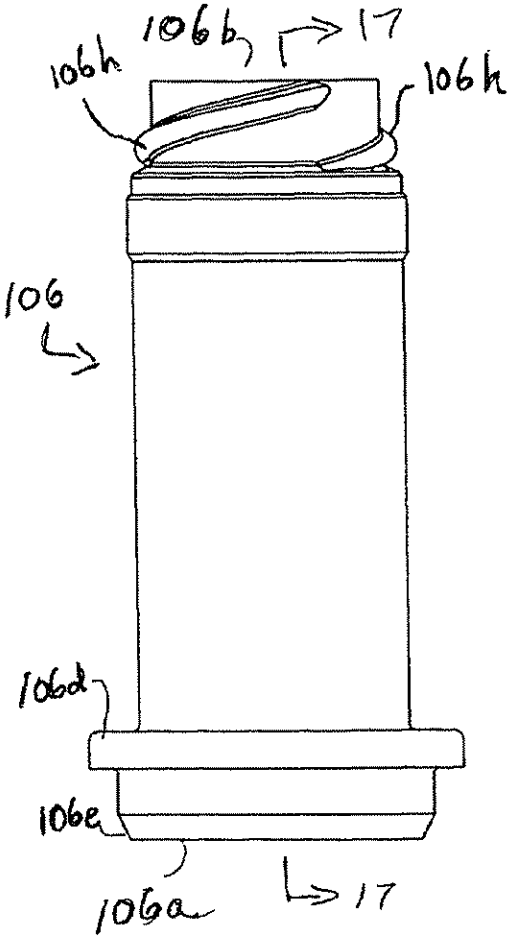
FIG. 17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17

FIG. 16

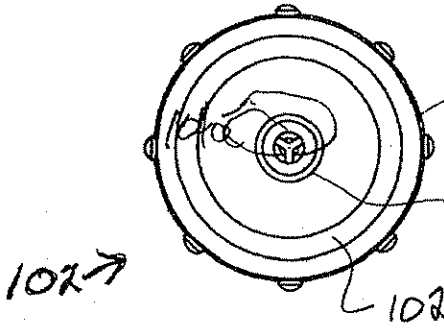

FIG. 19

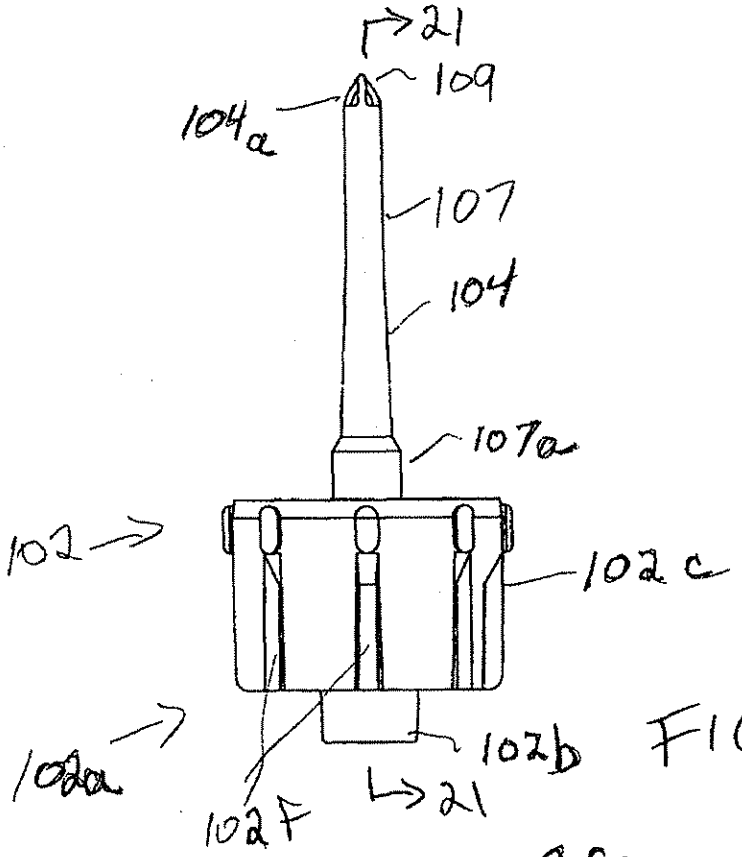

FIG. 18

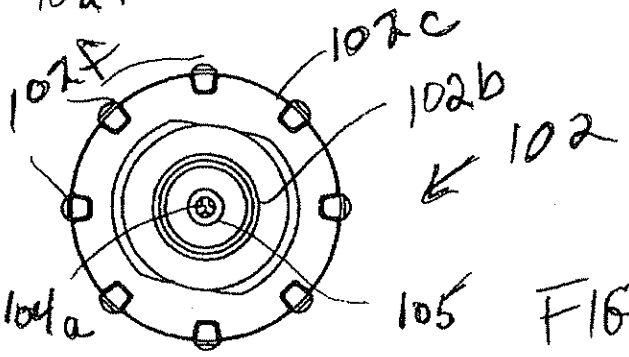

FIG. 20

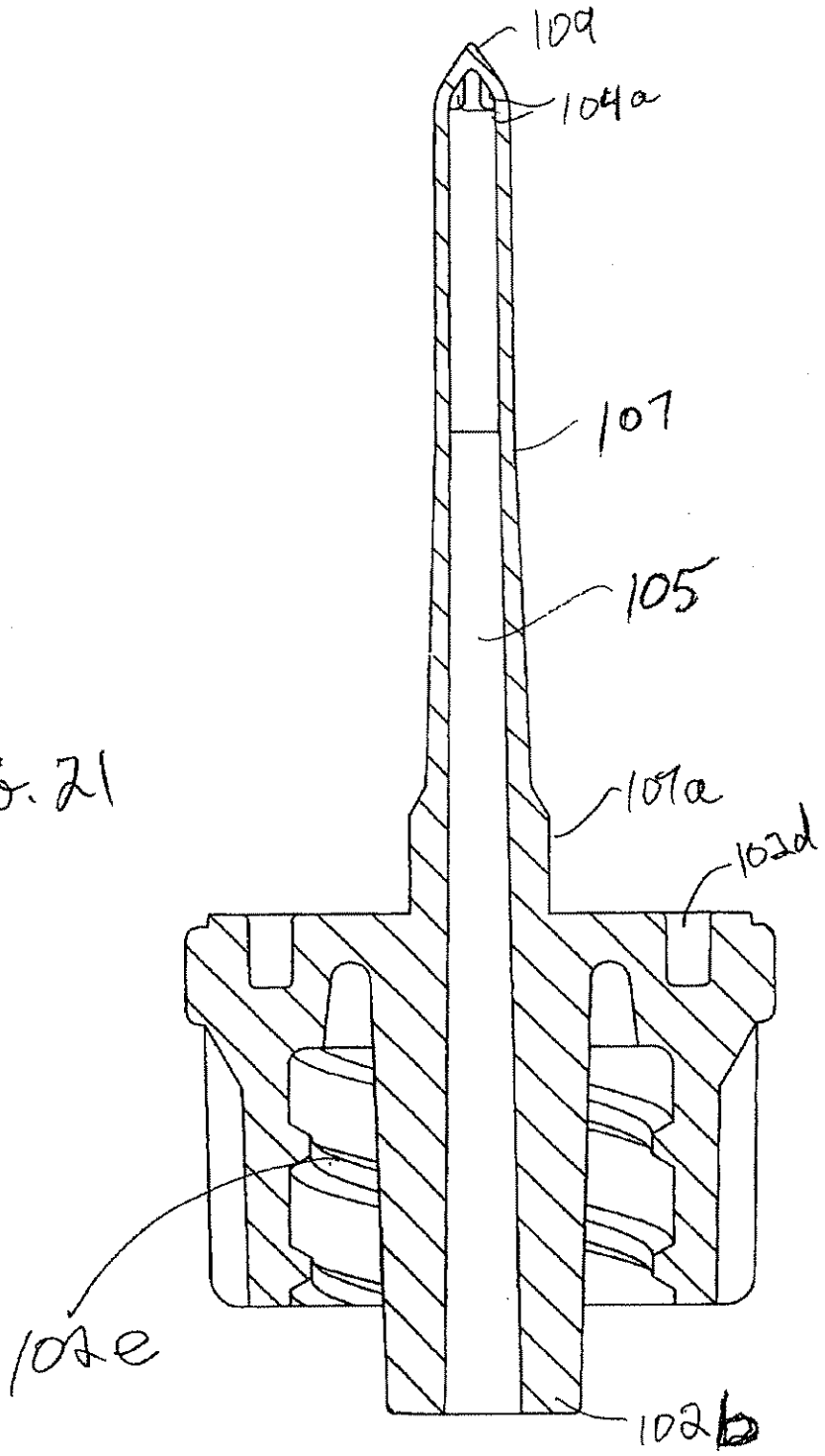

FIG. 21

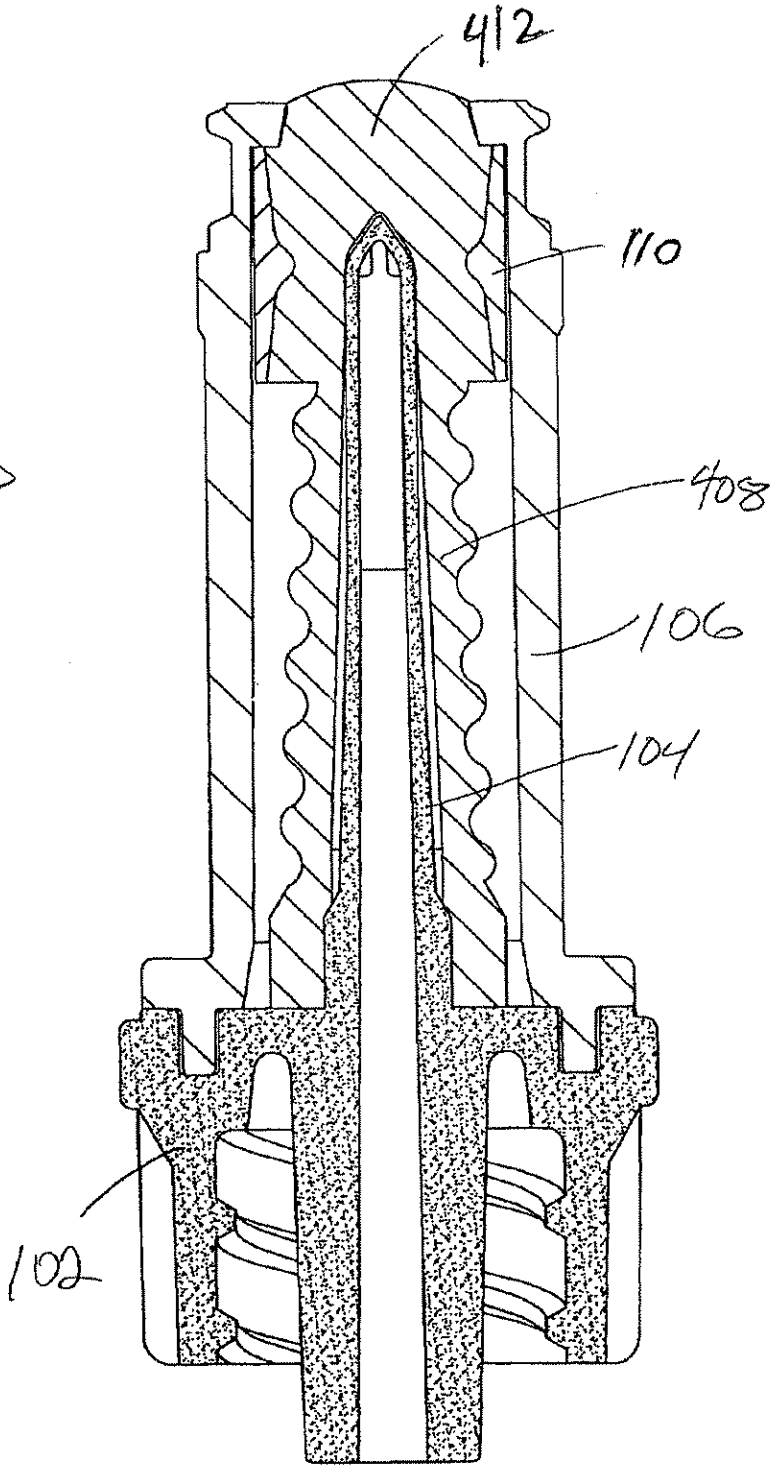

FIG. 22

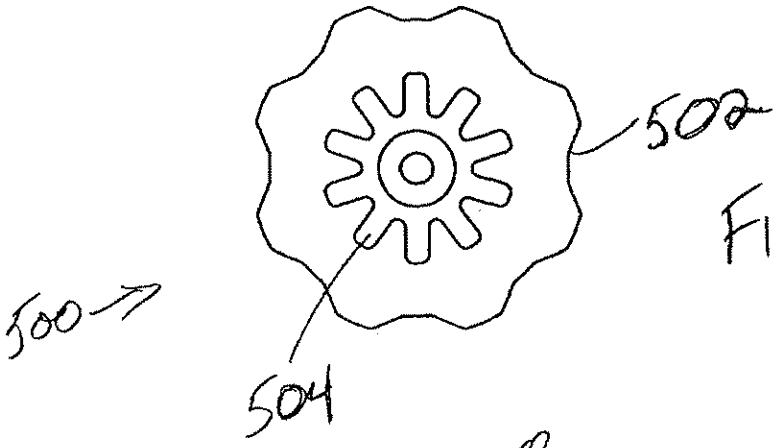

FIG. 24

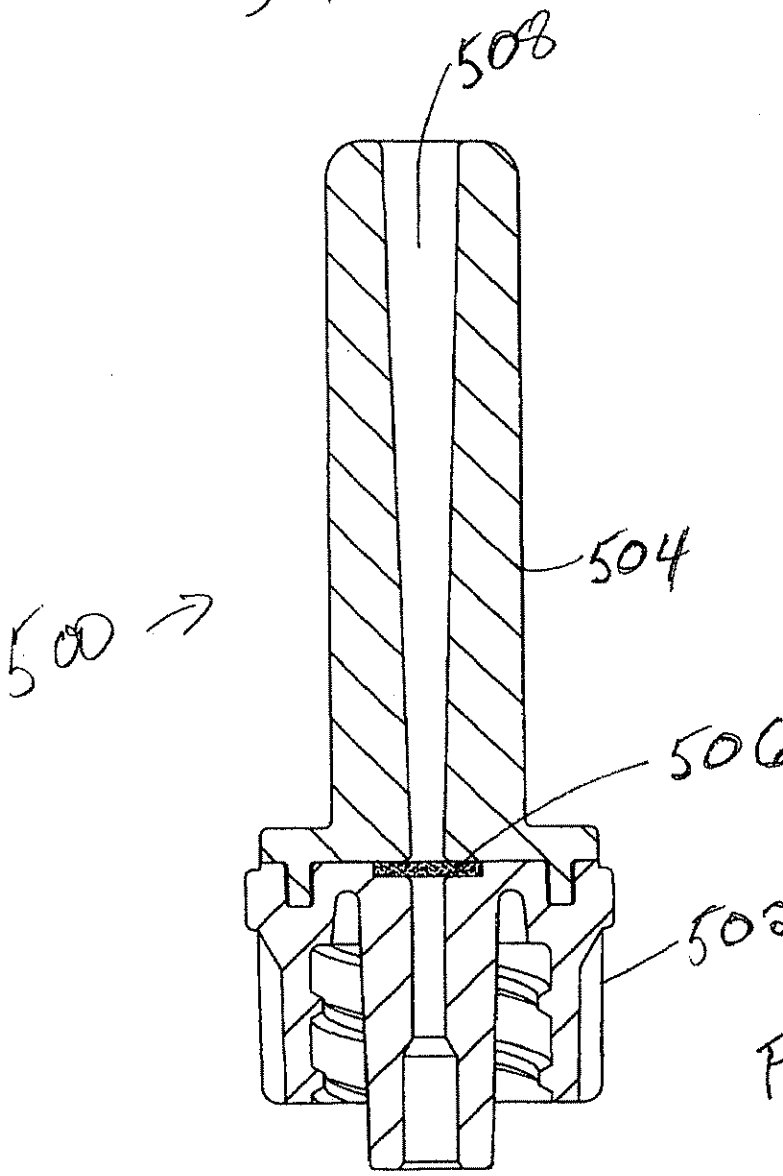

FIG. 23

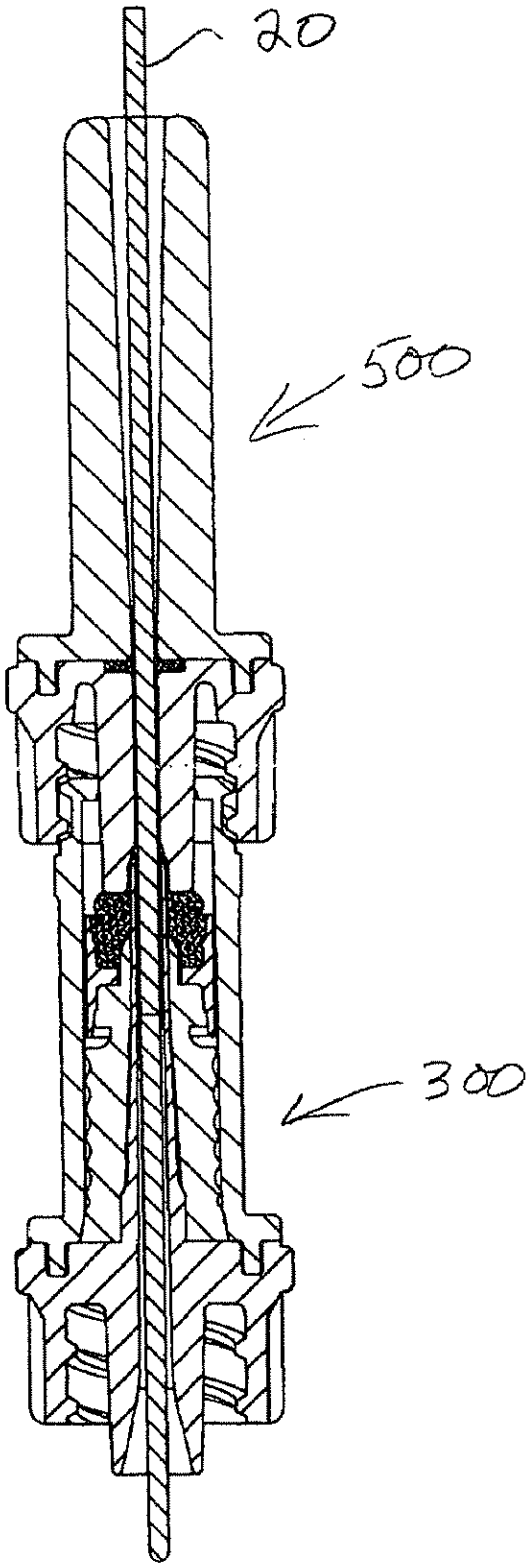

FIG. 25

SWABBABLE NEEDLE-FREE INJECTION PORT VALVE SYSTEM WITH NEUTRAL FLUID DISPLACEMENT

This application is related to U.S. Pat. No. 6,113,068, the complete disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to medical intravenous administration line connectors. More particularly, this invention relates to needle-free intermittent injection ports for the safe infusion and/or aspiration of fluids in intravenous and blood administration therapy.

2. State of the Art

Intravenous fluid therapy for parenteral administration or blood sampling in healthcare facilities routinely uses intermittent injection port connectors. These connectors or adapters are connected to a vascular access device such as a peripheral intravenous catheter, peripherally inserted central venous catheter, jugular, subclavian, and femoral central venous catheter, Huber needle, short-term needle, catheter and intravenous extension set, or intravenous administration set. The intermittent injection port connector allows the infusion therapist a means to infuse fluids or aspirate the patient's blood through the connector without having to stick the patient with a needle each time.

Traditionally, healthcare providers worldwide have used an intermittent injection port connector utilizing a latex septum or barrier requiring a hollow steel needle attached to a syringe or intravenous line set to pierce the resilient latex septum opening up a fluid channel to the patient. Since the discovery in the mid-1980's of the virus that causes AIDS, and the possibility of this virus being transmitted to the healthcare provider via an accidental needlestick injury, a major change within the medical device industry has taken place. Although hepatitis B and C are still the leading concern among healthcare professionals via an accidental needlestick injury, the emotional concern of the possibility of contracting AIDS through contaminated needles has been the catalyst for change in the industry.

Since the mid 1980's, various design innovations have solved the accidental needlestick injury crisis among healthcare professionals. Now that healthcare professionals are comfortable that they are protected from accidental needlestick injuries when they use these types of safety injection port systems, they are beginning to focus on the patient safety aspects of these products. It is clear that a new generation of intermittent injection port designs is needed to improve and resolve concerns such as microbial ingress, negative fluid displacement retrograding blood up into the catheter lumen, and other critical functional features.

Co-owned U.S. Pat. No. 6,113,068 focuses on improving upon the critical microbial barrier performance and functional attributes important for overall patient safety. After manufacture, it effectively provides a single piece injection port with standard male-luer connectors, i.e. universal access. No extra adapters, components, or end caps are required, thereby reducing the overall cost to deploy the system throughout the healthcare facility. The upper septum is swabbable and easy to disinfect. There are no gaps between the septum and the outer body opening. This prevents gross particulate contamination from entering into the internal body of the valve, thereby minimizing downstream contamination. The injection port cannot be used with non-safety hollow bore needles, thereby complying with OSHA guidelines and mandates. The double microbial barrier design is an effective barrier to pathogen ingress. The combination of the double resilient barriers (the upper resilient septum and the lower resilient boot valve) and their association with the hollow bore spike and centering component significantly reduce the negative fluid displacement to a negligible 0.0035 mL. The plastic centering component captures both barriers allowing the double barriers to move freely along the inner wall of the outer body and to keep the slits axially aligned with the spike tip and shaft. The straight-through fluid path eliminates the torturous paths found in some prior art devices. Priming volume is reduced to only 0.034 mL of fluid which is one of the smallest volumes for swabbable injection port connectors. Activation force to fully access the valve is approximately 5.5 lbs, an acceptable amount for the clinician while providing excellent snap-back. In the device described in my prior patent, fluid flow at gravity averaged 7,500 mL per hour thereby exceeding the ISO standard of 6,000 mL per hour with the fluid source at one meter above the valve. In the manufacturing process, after assembly of all the components and the sonic-welding of the two outer bodies, an ISO male luer fixture could be used to initially pre-puncture the two silicone barriers. As the male luer fixture is attached to the injection port assembly, the internal spike punctures the two silicone barriers and distributes the liquid silicone lubricant along the puncture axes in the two barriers.

Although the invention which is described in U.S. Pat. No. 6,133,068 improved upon many of the desired patient safety attributes for a swabbable injection port connector system, the prior design may be improved.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide a needle-free medical valve injection port which is safe, efficacious, and easy to use.

It is also an object of the invention to provide an injection port valve system which is swabbable and provides an excellent microbial ingress barrier protection.

It is another object of the invention to provide an injection port valve system which has a neutral fluid displacement to minimize blood being refluxed or retrograded into a vascular access device lumen during both the "connection to" and "disconnection from" the medical valve.

It is a further object of the invention to provide an injection port valve system which has improved snap-back characteristics in repeated use over the life cycle of the product to minimize fluid leakage and/or microbial ingress.

Another object of the invention is to provide an injection port valve system which minimizes dead space within the fluid pathway thereby reducing the probability of downstream contamination and improving the flushing capabilities of the medical valve.

A further objective of the invention is to provide an injection port valve system which has excellent leak resistant characteristics of repeated use during its life cycle.

An additional object of the invention is to provide an injection port valve system which improves the lubrication of the spike shaft, spike tip, and the puncture axis geometry to minimize coring of the two resilient microbial barriers during repeated use.

Yet another object of the invention is to provide an injection port valve system which has improved high back-pressure leak resistant capabilities.

It is even a further object of the invention to provide an injection port valve system which is easy to use and activate by reducing the overall activation force required.

In accord with these objects, which will be discussed in detail below, an injection port valve system according to the invention has five total components: an upper plastic outer body with ISO compliant threads ("the female luer body"), a lower plastic outer body with an integrally formed unitary hollow spike and an ISO compliant male luer lock in fluid communication with the spike ("the spike body"), an upper resilient barrier ("the septum"), a plastic centering and barrier cage ("the H-guide"), and a lower resilient barrier ("the boot valve").

The septum and the boot valve are designed to minimize fluid leakage from the patient side of the valve at high pressure (e.g. when the IV tubing is kinked or clogged) and to prevent microbial ingress from the outside environment into the patient's bloodstream. The septum and the boot valve are joined at the H-guide. The valve also includes a hollow spike having an open tip. The spike preferably has a bullet-nose bridge structure with at least two fluid opening channels or an unobstructed opening. The boot valve completely covers the spike giving the valve the first barrier of defense against fluid leakage to the outside environment and the second barrier of defense against microbial ingress from the outside environment into the patient's bloodstream. The septum provides the first barrier of defense against microbial ingress from the outside environment into the patient's bloodstream, and the second barrier of defense against fluid leakage to the outside environment. There is no dead space between the septum and the boot valve. There is also no dead space between the spike tip bridge and the inner wall of the boot valve. According to one embodiment, there is an internal ring seal protruding from the inner wall of the boot valve positioned just below the spike tip opening that has an interference fit with the spike shaft to prevent fluid blow-by down the outer surface of the spike. There is preferably an interference fit between the septum and the boot valve, as well as an interference fit between the H-guide and the two resilient barriers. The boot valve is sufficiently resilient to move the two resilient barriers and the H-guide immediately back to the original decompressed state upon the removal of a male luer connector from the female luer. The septum is preferably provided with an outer shoulder or flange, a tapered end facing the boot valve, a matching contour mating surface for mating with the boot valve, and a single continuous swabbable surface facing away from the boot valve and exposing the septum surface to the outside. The boot valve is preferably provided with a spring-like "helical" external surface. The septum and the boot valve are preferably pre-punctured with a solid core needle having a diameter of approximately 0.072 inches which is lubricated with a fluorosilicone liquid formulation. The surface of the spike is preferably roughened and coated with a fluorosilicone lubricant.

The medical valve of this invention has many features; no single one is solely responsible for its improved microbial and functional attributes. The system achieves a neutral fluid displacement and an improved microbial ingress barrier. There is no retrograde of the patient's blood up into vascular access devices such as a central venous catheter either during the "connection to" or the "disconnection from" the female luer.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** is an exploded perspective view of a first embodiment of the invention;

FIG. **2** is a longitudinal cross-sectional view of the assembled components of FIG. **1**;

FIG. **3** is a perspective view of a first embodiment of a boot valve according to the invention;

FIG. **4** is a broken longitudinal cross-sectional view of the assembled components of FIG. **2** and a standard male luer syringe positioned to activate the valve;

FIG. **5** is a view similar to FIG. **4** showing the valve activated by the standard male luer syringe;

FIG. **6** is a view similar to FIG. **2** showing the assembled components in conjunction with a multiple-dose drug vial adapter;

FIG. **7** is a longitudinal cross-sectional view of a Y-injection port according to the invention;

FIG. **8** is a view similar to FIG. **2** illustrating an alternate spike body;

FIG. **9** is an enlarged side elevational view of a septum according to the invention;

FIG. **10** is a section taken along line **10**—**10** in FIG. **9**;

FIG. **11** is an enlarged side elevational view of an H-guide according to the invention;

FIG. **12** is a top view of the H-guide of FIG. **11**;

FIG. **13** is a section taken along line **13**—**13** in FIG. **11**.

FIG. **14** is a side elevational view of a second embodiment of a boot valve according to the invention;

FIG. **15** is a section taken along line **15**—**15** in FIG. **14**;

FIG. **16** is an enlarged side elevational view of a female luer body according to the invention;

FIG. **17** is a section taken along line **17**—**17** in FIG. **16**;

FIG. **18** is a side elevational view of a spike body according to the invention;

FIG. **19** is a top plan view of the spike body of FIG. **18**;

FIG. **20** is a bottom plan view of the spike body of FIG. **18**;

FIG. **21** is an enlarged section taken along line **21**—**21** in FIG. **18**;

FIG. **22** is a view similar to FIG. **2** illustrating a single piece combination septum and boot valve;

FIG. **23** is a longitudinal sectional view of a guide wire adapter for use with the injection port system of the invention;

FIG. **24** is a top plan view of the guide wire adapter of FIG. **23**; and

FIG. **25** is a longitudinal sectional view of the guide wire adapter of FIG. **23** coupled to an injection port system of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to FIGS. **1**–**3**, a first embodiment of a needle-free intravenous injection port assembly **100** according to the invention generally includes a spike body **102** provided with a hollow spike **104**, a female luer connector component **106** (preferably a luer lock), a flexible and resilient boot valve **108**, an H-guide centering member **110**, and a resilient septum **112**. As seen best in FIG. **2**, the boot valve **108** extends over the spike **104**, the H-guide **110** is provided over a portion of the boot valve **108**, and the septum **112** is provided between the H-guide **110** and an end of the female luer connector component **106**. The spike body **102** and the female luer connector **106** are preferably made from a hard plastic material such as polycarbonate. The

H-guide **110** is preferably made from a soft plastic such as high density polyethylene. The boot valve **108** and the septum **112** are preferably made from a rubber-like material, such as polyisoprene or silicone rubber, having an approximately 60 Shore A Durometer.

According to the illustrated embodiment and as shown in larger view in FIG. **3**, the boot valve **108** is preferably configured with a helical external surface **108***a* and a radially enlarged portion **108***b*. The septum **112** is preferably provided with a shoulder **112***a*, a tapered end **112***b* facing the boot valve, and a single continuous swabbable surface **112***c* facing away from the boot valve as described in more detail below with reference to FIGS. **9** and **10**. The septum and the boot valve are preferably pre-punctured with a solid core steel needle approximately 0.072" diameter by aligning the septum and the boot valve in the H-guide in a subassembly and puncturing the septum and the boot valve in a pre-assembly manufacturing process as described below. The H-guide **110** is preferably provided with a tapered internal surface **110***a*, **100***b* at both ends and its outer surface **110***c* is polished very smooth as described in more detail below with reference to FIGS. **11–13**. The surface of the spike **104** is preferably roughened and is coated with a fluorosilicone lubricant. The roughened finish may be achieved by several methods including, but not limited to, EDM, sandblasting, media blasting, chemical etching, mechanical means, etc. The roughened finish helps to "entrap" the lubricant. The radially enlarged portion **108***b* of the boot valve **108** is preferably tapered to match the taper of the H-guide **110**. The boot valve **108** and the septum **112** are preferably mated with mechanical interference.

Turning now to FIGS. **4** and **5**, a needle-free syringe **10** has a male luer tip **10***a* which is matable with the female luer **106** of the invention. The male luer tip **10***a* is pressed against the swabbable surface **112***a* of the septum **112** and pushed down in the direction of the arrows shown in FIG. **4**. As the male luer **10***a* is moved into the female luer **106**, the septum **112** and the boot valve **108** are moved over the spike **104** as shown in FIG. **5**. This opens a fluid path between the interior of the luer **10***a* and the interior of the spike **104** due to holes in the top of the spike as discussed below with reference to FIGS. **18–21**.

FIG. **6** illustrates how the invention can be used with a multiple dose drug vial adapter **12**. The drug vial adapter **12** has a female luer **12***a* at one end and a hollow spike **12***b* at the other end. The male luer **102** of the injection port system **100** engages the female luer **12***a* of the drug vial adapter and the spike **12***b* of the vial adapter pierces the septum of a drug vial (not shown).

FIG. **7** illustrates a Y-site **200** incorporating an injection port according to the invention. The Y-site **200** has a Y-site base **202** which includes a spike **204** which is the same or similar to the spike **104** described above. The remaining components are the same as described above. Those skilled in the art will appreciate that the Y-site is useful when incorporated into an intravenous extension or administration set to allow injections via the same intravenous line through the injection port.

FIG. **8** illustrates an alternate embodiment of an injection port **300**. The injection port **300** has a spike body **302** with a spike **304** which does not have a point. It has, instead, an open tip **304***a*. The remainder of the components are the same as described above. This embodiment allows for the passage of guide-wires and other implements through the valve as described below with reference to FIGS. **23–25**.

FIGS. **9** and **10** illustrate enlarged views of the septum **112**. The septum **112** has an upper frustrum **112***d* and a lower frustrum **112***b* of larger diameter defining a shoulder **112***a*. The upper end of the upper frustrum **112***d* is a continuous convex surface **112***c*. The lower frustrum **112***b* defines a concavity **112***e* which is dimensioned to fit the tip of the boot valve with mechanical interference.

The upper resilient septum **112** provides the first line of defense against pathogen ingress into the fluid pathway from outside the injection port, and the second line of defense against fluid leakage due to high back pressure from inside the injection port. The septum is held in the "H-Guide" **110** as shown in FIG. **2** with a dimensional interference causing a circumferential mechanical force to assist in resealing the pre-puncture (not shown) in the center of the septum during numerous activations. The outer shoulder or flange **112***a* has a larger diameter than the opening of the female luer component **106** and the upper frustrum **112***d* preferably makes an interference fit with the female luer opening as seen in FIG. **2**.

As previously mentioned, the septum is preferably pre-punctured prior to assembly of injection port with a lubricated piercing device. The pre-puncturing process is performed with the septum, H-guide, and boot valve sub-assembly and a piercing device which moves through the two independent and adjacent resilient barriers until the piercing device is totally through the sub-assembly. The piercing device, preferably a 0.072 inch diameter solid core stainless steel needle (but other appropriate piercing devices would be acceptable), pre-punctures both the boot valve and septum in a smooth, in-line, axis geometry. This new smooth, in-line, axis geometry coupled with the fluorosilicone lubricant has reduced the required activation force to approximately 3.8 lbs, making it easier to use. This manufacturing process modification eliminates the jagged cuts, tears, and coring that was observed in the original process utilizing the internal spike tip. The piercing device is lubricated preferably with a fluorosilicone lubricant which assists in a smooth pre-puncture-axis geometry. The fluorosilicone formulation also minimizes the "cross-linking" of the silicone molecular structure. It is understood that other FDA approved lubricants could be acceptable for this application. In addition, in order to improve the decompression "snap-back" characteristics of this new injection port, and to minimize frictional abrasions within the silicone septum and boot valve during the compression or activation phase when the septum and boot valve move down over the internal spike tip and shaft, an inert lubricant is molded within the silicone septum and boot valve formulations. Silicone is the preferable material in this injection port due to its inertness, abrasive resistance, sealing and internal memory characteristics, and its sterilization capability. It is understood that other inert resilient materials could be used for this application.

Turning now to FIGS. **11–13**, the H-guide centering member **110** includes a generally tubular outer portion **110***c* and an annular inner portion defining a hole **110***d*. The outer portion **110***c* is sized to stably axially slide within the central portion of the female luer component **106** as shown in FIG. **2**. The outer portion **110***c* and inner portion together define first and second substantially identical receiving areas **110***a*, **110***b*. These areas have an outer tapered portion and an inner non-tapered smaller diameter portion. This assists in mating with the boot valve and the septum. The receiving areas **110***a*, **110***b* are preferably provided with annular rings **110***e*, **110***f* which assist in sealing the interface s between the septum and the boot valve.

FIGS. **14** and **15** illustrate a second alternate embodiment of a boot valve. There are two differences between this

embodiment and those described above. One is that undulations **208***a* are not helical but consist of a plurality of non-tapering rings arranged along the axis of the boot valve **208**. The other is the presence of an interior sealing ring **208***d*. Although this boot valve may not perform as well as the boot valve **108** in terms of snap back, it does retain the advantages of the frustrum **208***b*, the dimensions of the tip **208***c*, and the sealing ring **208***d* which helps seal the space between the boot valve and the spike shaft.

FIGS. **16** and **17** illustrate enlarged views of the female luer component **106**. The female luer connector component **106** is tubular and includes a first open end **106***a*, a female luer second end **106***b*, and a central portion **106***c* therebetween. The first end **106***a* includes a flange **106***d* which is preferably provided with an annular mating ridge **106***e*. The ridge defines an enlarged diameter relative to the central portion **106***c*, and is provided on the flange **106***d* directed away from the second end **106***b*. The mating ridge **106***e* is sized and shaped to be received in the annular mating slot of the spike body **102** (described below with reference to FIGS. **19** and **21**). The second end **106***b* includes an opening having a reduced (relative to the rest of the component **106**) with a tapered portion **106***f* and a non-tapered portion **106***g*. The tapered and non-tapered portions provide a better sealing fit with the septum **112** as shown in FIG. **2**. A luer lock thread **106***h* is preferably provided about the second end **106***b*.

The internal wall **106***j* of the component **106** is preferably smooth and slightly tapered up to a perpendicular wall **106***k*, leading to an opening approximately 0.180 inch diameter which preferably tapers to approximately a 0.164 inch diameter in the second end **106***b* of the female luer body component. The internal wall is preferably smooth to allow the H-guide component to axially move without obstruction during the compression and decompression phases. It is understood, that a fluted internal wall structure could also be acceptable.

FIGS. **18** through **21** illustrate the spike body **102** in greater detail. The spike body includes a first end **102***a* having a male luer connector **102***b*, the spike **104** preferably integrally formed with the body **102** and coaxially directed opposite the male luer connector **102***b*, and a base **102***c* at the juncture of the male luer connector **102***b* and the spike **104**. A fluid path **105** is provided through the spike **104** and male luer connector **102***b*. The spike **104** has a tapered shaft **107** leading to a bullet-nose arched tip **109** which defines a second end of the spike body **102**. The tip **109** includes a plurality of slots (e.g., three slots) **104***a* which provide access into the hollow **105** of the spike **104** from outside the spike. The shaft **107** includes a base portion **107***a* which has an enlarged stepped diameter for holding the boot valve thereabout. The base **102***c* of the spike body **102** also includes an annular groove **102***d* which receives the mating ridge **106***e* of the female luer component **106**. The base **102***c* preferably also includes a plurality of internal threads **102***e* which together with the male luer connector **102***b* function as a male luer lock. In addition, the periphery of the base **102***c* includes a plurality of molded longitudinal ridges **102***f* to facilitate engagement of the periphery of the spike body by human fingers.

As mentioned above, a preferred embodiment of the integral spike shaft and spike tip used in the present invention is configured with a roughened finish external surface and a fluorosilicone liquid lubricate used along the shaft and tip. The roughened finished external surface creates a roughened surface with approximately 0.001 to 0.002 inch depth areas allowing for a circumfluent flow of the liquid lubricant along the spike shaft and spike tip. The previously incorporated co-owned invention had a very smooth external spike shaft surface with a Dow **360** silicone lubricant. This smooth surface caused on occasion a "suction" affect between the internal wall surface of the boot valve component and the spike shaft. The roughened finish allows the lubricant to flow into the 0.001–0.002 inch impressions on the spike shaft, eliminating the "suction" effect seen in the prior invention, and maintaining adequate lubrication between the internal wall of the boot valve and spike shaft during numerous compression and decompression cycles of the valve. This surface improvement also enhances the "snap-back" feature of the valve.

From the foregoing, it will be appreciated that the female luer **106**, the septum **112**, the H-guide **110**, the boot valve **108**, and the spike **104** interact as described below to obtain numerous advantages. The septum **112**, by being properly dimensioned and entrapped within the female luer component when in the decompressed state passes a 60 psi back-pressure test, thus improving the prevention of fluid leakage from the injection port in high pressure situations (e.g. when the IV tubing is kinked or clogged). It also provides a primary seal surface to further prevent gross particulate contamination from entering into the body of the injection port, thus preventing pathogen ingress into the patient's blood stream. The interference fit between the septum and the female luer increases the circumferential mechanical force to improve the resealing of the pre-puncture in the center of the septum in the decompressed state.

The taper of the lower frustrum **112***b* assists in the assembly of the septum in the H-guide **110**. The lower frustrum **112***b* also has a larger diameter than the matching inside wall diameter of the H-guide causing a mechanical interference. This mechanical interference frictionally holds the septum into the H-guide.

The interior cavity **112***e* of the septum has a matching contour to the tip of the boot valve **108**. The diameter of this cavity is smaller than the tip of the boot valve, causing a circumferential mechanical fit against the pre-puncture in the boot valve. This new design eliminates any interstitial cavity chamber or dead space between these two interfaces thus assisting in achieving a "neutral fluid displacement" when the valve is moved from the decompressed state to the compressed state. The interference fit between the septum and the tip of the boot valve also improves the performance of the injection port in the decompressed state in the following ways. There is improved resealing of the pre-puncture in the center of the boot valve, improved prevention of pathogen ingress into the patient's bloodstream through the pre-puncture in the boot valve, and improved prevention of fluid leakage from the patient's side of the injection port due to a high pressure situation (e.g. when the IV tubing is kinked or clogged).

Another design modification that improves the overall performance of this new injection port is the provision of a single continuous swabbable surface on the proximal side of the septum. In addition all of the external surfaces of the septum that come in contact with the H-Guide and the boot valve are smooth to assist in the sealing characteristics between these component interfaces.

The new H-guide centering component assists in the new design enhancements and improvements. The H-guide contains both the upper resilient septum and the lower resilient boot valve. The outer diameters of the septum and the boot valve are larger than the inner wall diameters of the H-guide where they interface, giving a frictional fit between all components. The H-guide centering component is also shaped similar to the lead-in tapers of the septum and the

boot valve for ease of assembly. The dimensional mechanical interference between the septum and the H-guide applies a mechanical pressure against the pre-puncture axis of the two independent and adjacent resilient barriers, thereby improving microbial ingress prevention, improving fluid leakage prevention during high pressure situations (e.g. when the IV tubing is kinked or clogged), and assisting in eliminating the dead space between the septum/boot valve and boot valve/spike tip interfaces to achieve neutral fluid displacement during the compression and decompression cycle. The H-guide also prevents the two resilient barriers from coming in contact with the female luer inner wall, thereby eliminating any frictional abrasion during the compression and decompression cycle of the resilient barriers rubbing against the inner wall of the female luer body element, thereby, improving the "snap-back" capability of the valve. The H-guide also keeps the septum and boot valve in-line puncture axis geometry "centered" over the stationary spike tip and shaft, preventing jagged cuts, tears, or coring of the two resilient barriers. The outer diameter of the H-guide is slightly smaller than the inside diameter of the female luer body, allowing for a smooth axial movement of the valve during compression and decompression cycle. A preferred material for the H-guide is high-density polyethylene due to its lubricity characteristics, but other plastic materials could function in this application.

FIG. **22** illustrates another embodiment of an injection port **400** according to the invention. This embodiment differs from the first embodiment in that the boot valve **408** and the septum **412** are a single piece. All of the other components are the same as the first embodiment.

FIGS. **23** and **24** illustrate a guide wire adapter for use with an injection port according to the invention. The guide wire adapter **500** includes a male luer base **502** and an elongated female luer body **504** coupled to the male luer base with a thin silicone resilient disk **506** therebetween. The disk is preferably pre-punctured in its center. The silicone disk prevents air ingress into the patient's blood stream and prevents blood egress from the device. The female luer body **504** has a tapered inner bore **508** which is coaxial with the bore of the male luer **502**. The exterior of the female luer body **504** is fluted as shown in FIG. **24**. When the guide wire adapter **500** is coupled to an injection port **300** of FIG. **8** as shown in FIG. **25**, a guide wire **20** may be inserted through the adapter into and through the injection port.

There have been described and illustrated herein several embodiments of medical intravenous administration injection ports. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow. Thus, it will be appreciated by those skilled in the art that the term "intravenous fluid" is intended to be understood in a broad sense to include parenteral fluids including drug solutions, blood, blood products, dyes, or other fluids and the term "administration" is used in its broad sense to include the dispensing or collection of the "intravenous fluid". Further, while the injection port is illustrated as preferably having a female luer lock on one end, and a male luer lock on the other end, it will be appreciated that, although not preferred, simple luer slips could be utilized in lieu of luer locks. Furthermore, while a ridge and groove are disclosed for mating the female luer component and spike body together, it will be appreciated that other mating means may be used. For example, a plurality of mating tabs and slots, or ridges and grooves, or the like, may be used. Moreover, while a particular plastic material has been disclosed for the spike body, female luer component, and centering member, it will be appreciated that other rigid materials may likewise be used for these components. Also, in each embodiment the spike may be unitary with or of a separate construction than the body. Furthermore, while particular rubber-like materials have been disclosed for the boot valve and septum, it will be appreciated that other rubber-like materials of different Durometers may also be used. Further yet, while the boot valve and septum are described as preferably being pre-punctured with a solid core needle, it will be appreciated that, if desired, neither the valve nor the septum need be pre-punctured, or only one of them might be pre-punctured. Alternatively, although not preferred, the boot valve and/or septum may be pre-slit; i.e., formed with a horizontal slit therein. Pre-slitting the boot valve and/or septum is not preferred as during use the pre-slit boot and/or septum will not accommodate the spike as well as a pre-punctured boot and/or septum. It will therefore be more prone to tearing, thereby leaving the pre-slit device more prone to undesirable microbial migration. Also, while a boot valve having an outer helical surface and a smooth and tapered inner surface has been shown, it will be appreciated that the boot valve could also have a helical inner or other non-smooth or non-tapered surface. Therefore, it will be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as so claimed.

What is claimed is:

1. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted,

said resilient barrier includes a boot valve and a septum, and

said septum has a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a continuous convex surface.

2. An injection port assembly according to claim **1**, wherein:

said resilient barrier has a generally helical surface pattern.

3. An injection port assembly according to claim **2**, wherein:

said boot valve and said septum are pierced with a solid core needle prior to assembly of said injection port.

4. An injection port assembly according to claim **3**, wherein:

said needle has a diameter of approximately 0.072 inches.

5. An injection port assembly according to claim **1**, further comprising:

a body incorporating said first and second mating structures.

6. An injection port assembly according to claim **2**, wherein;

said boot valve and said septum are mated with mechanical interference.

7. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted, and

a spike mounted within said resilient barrier, said spike having a roughened surface which is covered with a lubricant.

8. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted, wherein said resilient barrier includes a boot valve and a septum having a lower frustrum, and

a centering means for axially centering said boot valve and said septum, said centering means having a first tapered opening dimensioned to accommodate said lower frustrum and a smooth outer periphery.

9. An injection port assembly according to claim 8, wherein:

said boot valve has a frustroconical extension and said centering means has a second tapered opening dimensioned to accommodate said frustroconical extension.

10. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient barrier extending over said spike and having a tip portion about said tip of said spike, said resilient barrier being pre-punctured with a solid core steel needle prior to assembly; and

d) a hollow component having a first end and a second end, said first end being coupled to said body, said hollow component extending around at least portions of said spike and said resilient barrier, and said second end being provided with a second mating structure adapted to removably couple to the second connector, wherein

when the second connector is coupled to said second mating structure, said second connector forces said tip portion of said pre-punctured resilient barrier over said spike such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

11. An injection port assembly according to claim 10, wherein:

said needle has a diameter of approximately 0.072 inches, and said spike has a roughened surface which is covered with a lubricant.

12. An injection port assembly according to claim 10, wherein:

said resilient barrier includes a boot valve and a septum mated with mechanical interference.

13. An injection port assembly according to claim 12, wherein:

said septum has a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a continuous convex surface.

14. An injection port assembly according to claim 13, further comprising:

e) a centering means for axially centering said boot valve and said septum relative to said spike, said centering means having a first tapered opening dimensioned to accommodate said lower frustrum.

15. An injection port assembly according to claim 14, wherein:

said boot valve has a frustroconical extension and said centering means has a second tapered opening dimensioned to accommodate said frustroconical extension.

16. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end provided with a second mating structure adapted to removably couple to the second connector;

b) a hollow spike coupled to and at least partially surrounded by said body, said hollow spike having a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient first barrier extending over said spike and having a tip portion about said tip of said spike; and

d) a resilient second barrier provided over and contacting said tip portion of said first barrier, said first and second barriers being mated with mechanical interference, wherein

when the second connector is coupled to said second mating structure, said second connector forces said second resilient barrier and said tip portion of said first resilient barrier over said spike with neutral fluid displacement and such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

17. An injection port assembly according to claim 16, wherein:

said resilient second barrier has a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a continuous convex surface.

18. An injection port assembly according to claim 16, further comprising:

e) a centering means for axially centering said first barrier and said second barrier relative to said spike, wherein said resilient second barrier has a lower frustrum and said centering means has a first tapered opening dimensioned to accommodate said lower frustrum.

19. An injection port assembly according to claim 18, wherein:

said resilient first barrier has a frustroconical extension and said centering means has a second tapered opening dimensioned to accommodate said frustroconical extension.

20. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end provided with a second mating structure adapted to removably couple to the second connector;

b) a hollow spike coupled to and at least partially surrounded by said body, said hollow spike having a shaft having a roughened outer surface and coated with a lubricant and a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other; and

c) a resilient barrier extending over said spike and having a tip portion about said tip of said spike;

when the second connector is coupled to said second mating structure, said second connector forces said tip portion of said resilient barrier over said spike such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

21. An injection port assembly according to claim 20, wherein:

said lubricant is a fluorosilicone.

22. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end provided with a second mating structure adapted to removably couple to the second connector;

b) a hollow spike coupled to and at least partially surrounded by said body, said hollow spike having a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient first barrier extending over said spike and having a tip portion about said tip of said spike; and

d) a resilient second barrier provided over and contacting said tip portion of said first barrier, said second barrier having a lower frustrum and an upper frustrum of different diameter defining a shoulder, said upper frustrum having a single continuous swabbable surface, wherein

when the second connector is coupled to said second mating structure, said second connector forces said second resilient barrier and said tip portion of said first resilient barrier over said spike such that said second connector and said first connector are in fluid communication with each other through said hollow spike and said first mating structure.

23. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient barrier extending over said spike, wherein

when the second connector is coupled to said second mating structure, the second connector forces said resilient barrier over said spike with neutral fluid displacement and such that the second connector and the first connector are in fluid communication with each other through said hollow spike and said first mating structure.

24. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient first barrier extending over said spike and having a tip portion about said tip of said spike;

d) a resilient second barrier provided over and contacting said tip portion of said first barrier, wherein

there is no dead space between said first barrier and said second barrier and no dead space between the tip portion of the first barrier and the tip of the spike.

25. An injection port assembly according to claim 24, further comprising:

e) a multiple dose drug vial adapter coupled to said first end of said hollow spike.

26. An injection port assembly according to claim 24, further comprising:

e) a y-site adapter coupled to said first end of said hollow spike.

27. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for receiving and passing a fluid into the first fluid pathway from a device provided with a second connector, said injection port assembly comprising:

a) a body having a first end provided with a first mating structure adapted to mate with the first connector, and a second end;

b) a hollow spike defining a shaft having a first end coupled to said body and a second end provided with a penetrating tip, said first mating structure and said hollow spike being in fluid communication with each other;

c) a resilient barrier extending over said spike, wherein said penetrating tip is truncated with an open tip; and

a guide wire adapter including

a male luer adapted to be coupled to said first end of said body;

an elongated member having a tapered throughbore, said elongated member being coupled to said male luer; and

a pierceable fluid barrier mounted between said male luer and said elongated member.

28. A method for coupling and uncoupling a device to a fluid pathway, said method comprising:

coupling an injection port assembly having a valve to the fluid pathway,

coupling the device to the injection port assembly such that the valve is opened putting the device is in fluid communication with the fluid pathway with neutral fluid displacement during coupling.

29. The method according to claim **28**, further comprising:

uncoupling the device from the injection port assembly such that the device is no longer in fluid communication with the fluid pathway with neutral fluid displacement during uncoupling.

30. An injection port assembly for coupling to and uncoupling from a first fluid pathway of a first connector and for coupling to a device provided with a second connector so as to provide a fluid connection between the first and second connectors, said injection port assembly comprising:

a first mating structure adapted to mate with the first connector and a second mating structure coupled to said first mating structure and adapted to mate with the second connector,

a resilient barrier located between said first and second mating structures and movable from a first position in which fluid flow between said first mating structure and said second mating structure is blocked to a second position in which fluid flow between said first mating structure and said second mating structure is permitted, said resilient barrier being an integrally formed boot valve and septum, said septum having a pierceable portion which is substantially thicker than said boot valve and when said barrier is moved from said first position to said second position all of said septum is moved.

* * * * *

EXHIBIT C

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District
4040 North Central
Expressway
Dallas, Texas 75204-3128

February 9, 2007

Ref: 2007-DAL-WL-9

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQU ESTED

Mr. Dana William Ryan, President and CEO
Rymed Technologies, Inc.
137 3rd Avenue North
Franklin, Tennessee 37064

Dear Mr. Ryan:

During an inspection of your firm located at 6000 W. William Cannon Drive, Building B, Suite 300, Austin, Texas 78749 on October 18 through November 8, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures and markets the Invision-Plus® Neutral™ I.V. Connector Models RYM-500015001 and catheter extension sets intended for single patient use in intravenous and blood administration. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act} (21 U.S.C. § 321 (h)), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501 (h} of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS} regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

At the conclusion of the inspection, FDA issued to your firm a list of Inspectional Observations, Form FDA 483 {copy enclosed), which identified a number of significant QS Regulation violations including, but not limited to, those described below.

1. Failure to establish and maintain procedures for monitoring and control of process parameters for a validated process to ensure that the specified requirements continue to be met, as required by 21 CFR § 820.75(b). FDA 483

Item 7. Your firm's foreign contract manufacturer assembles and welds the molding pieces of referenced devices using a **[redacted]** welder provided by your firm. Your firm has neither monitored the validated welding process via an increased sampling plan nor reviewed the test results of the weld integrity of the female luer and the spike body in order to detect changes in the welding process which caused weld failures and your firm's subsequent recall of ten lots of the referenced devices.

2. Failure to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR § 820.100(a)(3). In May 2006, your firm initiated a recall of the referenced devices due to weld failures. However, your firm failed to ensure that all the affected lots of the referenced devices were effectively retrieved from the market and the users were adequately notified of your firm's recall to prevent further use of the nonconforming devices. For example, your firm received a user complaint on September 25, 2006 (Complaint Report 06012) which documented that the product came apart into pieces, and the samples of Lot 405 returned to your firm had weld failures. Your firm's complaint reports for another five user complaints documented that the users will be noted. However, there was no documentation proving that these users were in fact notified. In reviewing the FDA's Maude Reports, FDA identified two additional adverse events, dated 9/22/06 and 10/6/06, which reported that the device parts came apart or the device parts were disassembled.

3. Failure to ensure that information relating quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems, as required by 21 CFR § 820.100(a)(6), and failure to document the results of corrective action activities, as required by 21 CFR § 820.100(b). FDA 483 Item 4. For example, although your firm had a teleconference call with the foreign contract manufacturer and subsequently visited them to discuss the issue of weld failures and initiated additional testing and trouble shooting of your welding machine on April 3, 2006, your firm failed to maintain documentation of your teleconference call minutes, the test results of nonconforming Lot 509924, and the root cause of the misalignment of your **[redacted]**welding machine's components.

4. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all the requirements of 21 CFR § 820.198(a) through (e) are met. FDA 483 Item 2, 8, and 9. For example, in reviewing six of the eight complaints of weld failures, your firm failed to document sufficient detail to describe the complaints, including whether the devices were used on patients and whether any complications occurred, and to include in the complaint file adequate records of complaint investigations.

5. Failure to establish and maintain procedures for the identification, documentation, validation or verification, review, and approval of design changes before their implementation, as required by 21 CFR § 820.30(i), and failure to establish and maintain a design history file for each type of device which contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan, as required by 21 CFR § 820.30(j). FDA 483 Item 5 and 6. Your firm failed to establish and maintain a design history file for the referenced devices according to your Design Control Plan, Procedure 110, effective dated 11/2/98. Your design change records are incomplete in that you failed to maintain design verification or validation results for a design modification to the Invision-Plus® Neutral™ I.V. Connector from the RYM-3000 series to RYM-5000 series. Our inspection also revealed that your above-referenced devices are also misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by or under by Section 519(f)(1) of the Act, 21 U.S.C. § 360i(f)(1), and 21 CFR § 806 - Reports of Corrections and Removals Regulation. FDA 483 Item 1. Significant

deviations include, but are not limited to, the following:

1. Failure to promptly report to FDA any correction or removal of a device to reduce a risk to health within 10 working days, as required by 21 CFR § 806.10 (a)(1). FDA 483 item 1. For example, the inspection documented that in May 2006, your firm contacted your independent distribution centers to have them return the specific lots of devices due to incomplete welds between the **[redacted]** and the **[redacted]**. Defective welds may result in patients not receiving adequate dosage of drugs, the patient's blood backing up (retrograding) into the catheter lumen and bleeding from your I.V. connector, air bubbles being trapped in the I .V. line, migration of the microorganisms, or disruption in I.V. therapy due to leakage. These conditions pose a potential risk to health. Your firm's action to retrieve the specific lots of the nonconforming devices to prevent their further use meets the definition of a "removal" in 21 CFR § 806.2(i), yet no report was submitted to FDA, in violation of 21 CFR § 806.10 (a)(1), which requires manufacturers or importers to submit a written report to FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health.

The above-referenced devices are further misbranded under Section 502(0) of the Act, 21 U.S.C. § 352(0), in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the Act, 21 U.S.C. § 360, and the Establishment Registration and Device Listing Regulation, 21 CFR § 807. You failed to update your firm's current establishment registration to list the address of your firm's manufacturing site at 6000 W. William Cannon Drive, Building B, Suite 300, Austin, Texas 78749. Your firm still lists its manufacturing site at your corporate office's address at 2154 Kidd Road, Nolensville, Tennessee 37135. This corporate office has moved to another address in Tennessee identified above.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, premarket approval applications for Class III devices to which the QS regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of these corrections. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Thao Ta, Compliance Officer, DAL-DO, Food and Drug Administration, HFR-SW440, 4040 N. Central Expressway, Suite 300, Dallas, TX 75240. If you have any questions about the contents of this letter, please contact Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Fom1 FDA-483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

/S/

Michael A. Chapell
Dallas District Office

MAC:TXT

cc:
Mr. Jim M. Kaiser, Vice President
Rymed Technologies, Inc.
6000 W. William Cannon Drive
Building B, Suite 300
Austin, Texas 78749

EXHIBIT D

Company Profile **Updated:** 07-DEC-07

Co-Medical Inc.

Private Company, Headquarters Location
7100 Roosevelt Way NE, Seattle, WA, United States
(206)524-7424, USA (206)524-7120 fax, http://www.comedical.com
Primary SIC: Commerical Equipment, Not Elsewhere Classified, Primary NAICS: Other Commercial Equipment Merchant Wholesalers
Description: Wholesale: Medical, Dental, and Optical Equipment

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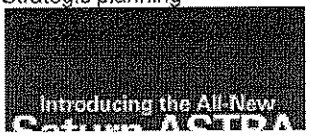

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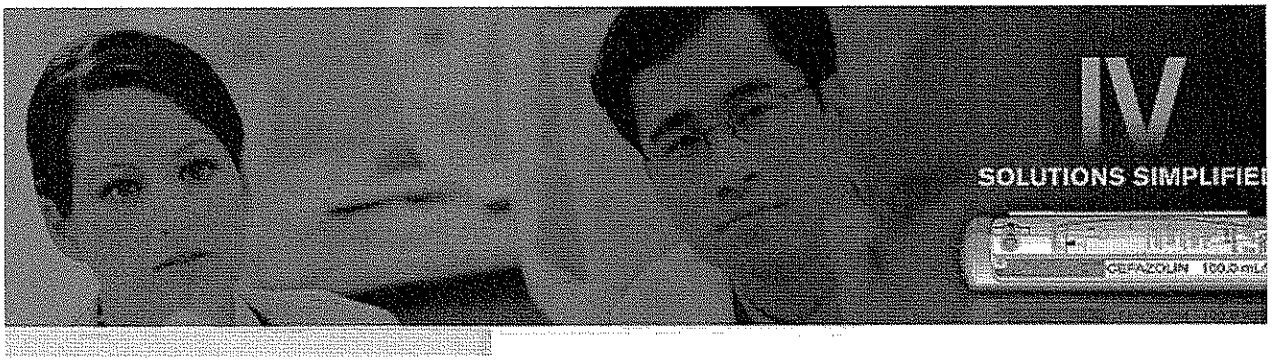
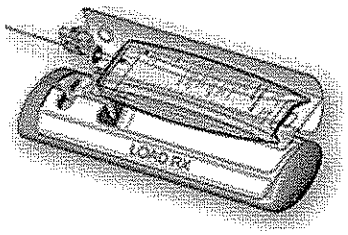
EXHIBIT E



Can you imagine?

An infusion system that can document significant improvements in nursing efficiency and patient safety while costing far less to own and operate than competitive systems?



Contact Us >>

Fluidnet was founded in 2002 by a group of medical device professionals who collectively have over 100+ years of industry experience and product innovations.

Based on the seacoast of scenic New Hampshire, Fluidnet is just north of Boston, providing access to a rich medical device community and first-rate research and development skills and facilities.

The company is relentlessly dedicated to explore, listen and respond to the unmet needs of customers.

22 different Clinical Leadership Seminars have been conducted across the country with over 500 infusion professionals who have contributed to the product development process of this innovative infusion system.

Fluidnet is committed to utilizing best-in-class medical device development, design, and software partners. Fluidnet is also proud to have its products manufactured and supported in partnership with MACK Corporation. (www.mack.com)

Fluidnet is currently preparing for a commercial release of the product within the US market in the first quarter of 2009.

The Fluidnet system has not yet been cleared by the FDA as a medical device for sale, distribution, or use on patients. The descriptions herein are for discussion purposes only.

EXHIBIT F

State of Delaware

The Official Website for the First State

Entity Details

THIS IS NOT A STATEMENT OF GOOD STANDING

File Number:	**3473161**	Incorporation Date / Formation Date:	**12/26/2001** (mm/dd/yyyy)
Entity Name:	**FLUIDNET CORPORATION**		
Entity Kind:	**CORPORATION**	Entity Type:	**GENERAL**
Residency:	**DOMESTIC**	State:	**DE**

REGISTERED AGENT INFORMATION

Name:	**THE CORPORATION TRUST COMPANY**		
Address:	**CORPORATION TRUST CENTER 1209 ORANGE STREET**		
City:	**WILMINGTON**	County:	**NEW CASTLE**
State:	**DE**	Postal Code:	**19801**
Phone:	**(302)658-7581**		

Additional Information is available for a fee. You can retrieve Status for a fee of $10.00 or more detailed information including current franchise tax assessment, current filing history and more for a fee of $20.00.

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